A STUDY ON FACTORS INFLUENCING THE QUALITY OF TOTAL MESORECTAL EXCISION

Dissertation

Submitted in partial fulfillment of the regulations of

M.S. DEGREE EXAMINATION

BRANCH I GENERAL SURGERY

Department of General Surgery

GOVT. STANLEY MEDICAL COLLEGE AND HOSPITAL

CHENNAI - 600001

THE TAMILNADU DR.M.G.R MEDICAL UNIVERSITY

CHENNAI

APRIL 2014

CERTIFICATE

This is to certify that this dissertation titled

A STUDY ON FACTORS INFLUENCING THE QUALITY OF TOTAL MESORECTAL EXCISION

is the bonafide work done by **Dr. Robin Prabhu I. ,** Post Graduate student (2011 – 2014) in the Department of General Surgery, Government Stanley Medical College and Hospital, Chennai under my direct guidance and supervision, in partial fulfillment of the regulations of The Tamil Nadu Dr. M.G.R Medical University, Chennai for the award of M.S., Degree (General Surgery) Branch - I, Examination to be held in April 2014.

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Place: Chennai.
Date: December 2013. **DR. ROBIN PRABHU I.**

ACKNOWLEDGEMENT

I am grateful to **Prof. S. Geethalakshmi,** Dean, Govt. Stanley Medical College for permitting me to conduct the study and use the resources of the College.

My sincere thanks to **Prof. K. Kamaraj,** Professor and HOD, Department of General Surgery, for his valuable guidance throughout the study.

I am highly indebted to my guide **Prof. S. Viswanathan**, Professor of Surgery for his constant help, inspiration and valuable advice in preparing this dissertation.

I express my deepest sense of thankfulness to my Assistant Professors **Dr. T. Babu Antony, Dr. C. Manimegalai, Dr. R. Abraham Jebakumar** for their valuable inputs and constant encouragement without which this dissertation could not have been completed.

I consider it a privilege to have done this study under the supervision of my beloved former Professor and Head of the Department **Prof. P. Darwin**, who has been a source of constant inspiration and encouragement to accomplish this work.

I am particularly thankful to my fellow postgraduate colleagues for their valuable support in the time of need throughout this study.

It is my earnest duty to thank my parents without whom accomplishing this task would have been impossible.

I am extremely thankful to my patients who consented and participated to make this study possible.

CONTENTS

A STUDY ON FACTORS INFLUENCING THE QUALITY OF TOTAL MESORECTAL EXCISION

Abstract

Background:
Total mesorectal excision (TME) has become the standard of care for rectal cancer. Incomplete TME has been found lead to local recurrence. The factors which impact the TME have been scarcely studied. In this study we plan to investigate those factors which affect the quality of TME.

Methods:
Data of patients undergoing resectional surgery for adenocarcinoma of the rectum were entered into the database. This data included age, sex, BMI, distance of tumor from anal verge, pathological tumor stage, use of neo-adjuvant therapy, surgical modality, duration of surgery, presence of intra-op complications and type of dissection technique. The specimen after surgery was examined both by the surgeon and the pathologist. It was classified either as optimal TME or sub-optimal TME. Statistical analysis was done using chi-square test for categorical variables and ANOVA for continuous variables.

Results:
Of a total 50 patient, 38 patients were found to have grade 1 TME, 8 with grade 2 TME and 4 with grade 3 TME. Significant association ($p<0.05$) was found between Pathological tumour category T4, presence of intra-operative complications, surgery lasting longer than 240 mins and use of monopolar or blunt dissection. No significance was seen with age of patient, gender, BMI of the patient, distance of tumor from anal verge, type of surgical approach or neo-adjuvant therapy,

Conclusion:
Negative impact on TME was found with distinctive disease and surgery related factors.

Key Words:
TME, Rectal carcinoma, mesorectum, dissection, Low anterior resection, Abdomino-perineal resection, recurrence, quality

INTRODUCTION

Colorectal malignancy is the second leading cause of cancer deaths and is one of the challenging problems encountered by surgeons today. Globally, nearly 800,000 new cases occur and death is estimated at nearly 450,000. Local recurrence after surgery may be largely related to technique used and leads to considerable morbidity. Mortality is generally related to the systemic spread of disease prior to surgical treatment. This problem has received wider attention over the past decade. Though earlier reported local recurrence neared 30%, [2] recent advances have reduced it to less than 10%. The two major advances in this period have been the use of neo-adjuvant therapy and change in surgical technique created by a better understanding of the local spread of rectal cancers. Modern surgery for rectal malignancy is based on a total mesorectal excision (TME) which involves sharp, complete extirpation of the cancer en bloc along a thin fascial layer which contains the surrounding perirectal lymphatic tissue. The description mesorectum refers to a fatty connective tissue layer of lymphatics, lymph nodes and associated vessels measuring 2–3 cm in thickness, which surrounds the rectum and is enveloped by fascia. Mesorectal excision refers to the excision of this soft tissue envelope under direct vision using sharp

instruments, dissecting between the visceral and parietal fascia. The embryonal plane between the parietal and visceral pelvic fasciae has been referred to as the "holy plane".[5] A mesorectal excision can be of two types - total (TME) or partial (PME) depending on the distal extent of surgery. It is said to be total if mesorectum is completely excised down to the pelvic floor and is indicated for malignancy of the middle and lower third of the rectum. Partial Mesorectal Excision is done for treatment of malignancy of the upper one third of the rectum[5] , although circumferentially it is performed in the same way as for Total, distally the mesorectum is transected perpendicular to the rectal wall at a distance of 5 cm beyond the distal most edge of the tumour;

Various Clinical studies have shown incomplete total mesorectal excision to be associated with increased local and overall recurrences. The factors which are significantly associated with incomplete mesorectal excision have scarcely been studied. In this regard, it becomes necessary to detect preoperative patient-, treatment- and disease- related factors that are associated with incomplete mesorectal excision.

AIMS & OBJECTIVES

The aim of my study is to

- Determine the patients undergoing surgery for rectal malignancy with adequate total mesorectal excision, and
- Identify the patient, disease and surgery related factors which influenced the quality of mesorectal excision .

HISTORY

The Romanian anatomist Thoma Jonnesco gave the first available description on the mesorectum, though he did not call it by that name. It was published in the *Traite d'Anatomie Humaine* which was authored by Poirier and Charpy in 1896. It remained unchanged in the second edition of the book. It was also referenced by Gerota[5] and Waldeyer[6] in their monographs on rectal anatomy. Jonnesco's observations dictated that the rectum was encapsulated within a thin fibrous sheath, which separated it from the other pelvic organs, and how the rectum could be mobilized easily from the sacrum and presacral vessels by proper respect for this fibrous sheath.[3]

The first to describe the procedure of total mesorectal excision[7] was Abel in 1931.[8] However, TME was given widespread attention by the English Surgeon Heald in 1979[9]. He reported from his clinical experience at the North Hampshire Hospital situated in Basingstoke, England. In his publication, he ascribed the method of TME and postulated the important steps in surgery for rectal malignancy. He emphasized on the use of direct vision and sharp dissection during the mobilization of the rectum to remain between the parietal and visceral pelvic fascia. Contemporary surgeons often have

argued, even prior to it being described as *total mesorectal excision*, that this technique was practiced by many others. Heald was still the first person to describe the steps of a formal proctectomy for rectal malignancy and demonstrated why deviation from this anatomical plane is unacceptable in modern surgery. He reported the lowest recurrence rates at that time. In his first series of 112 patients[2] he showed a 5-year survival of 87.5% and a 5-year local recurrence rate of 2.7%. Heald's extraordinary results were questioned by many at the time;[10] nevertheless, more recent series[11,12] with similar patients samples have reported similar recurrence rates and lend support to Heald's methods. Heald's publications have introduced TME as the surgical technique of choice[13], and have changed how the technique of proctectomy for cancer is taught throughout the world.

ANATOMY OF RECTUM

The Latin word ‘rectus’ means straight, and the rectum is found to be straight in monkeys, but since the human rectum follows the posterior concavity of the sacrum, it is curved. It also shows three lateral curves or flexures that are most prominent when the viscus is distended: upper and lower curves convex to the right and a middle curve convex to the left, hence the middle part appears to bulge to the left. The lowest part which is slightly dilated is known as the rectal ampulla. Corresponding to the three curves seen externally, internally there are three sickle-shaped transverse rectal folds, formerly called rectal valves (of Houston). They project into the lumen from the wall on the concave side of these folds. They incorporate the circular muscle of the wall and are not confined merely to the mucous membrane, as is the case with the circular folds of the duodenum and jejunum. The middle fold which is the largest, projects into the lumen from the right wall of the rectum just above the ampulla, at the level at which the peritoneum is reflected forwards off the rectum to form the floor of the rectovesical or rectouterine pouch; it is about 8 cm from the anal orifice and is a useful landmark during colonoscopy.

The rectum, which is about 12 cm long, continues as the sigmoid colon at the level of the third segment of the sacrum. There is no clear transition between the rectum and the sigmoid colon. At this region the sigmoid mesocolon ends gradually and the rectum starts, which has no mesentery. The taeniae of the sigmoid colon widen to form anterior and posterior muscular bands, which meet laterally to give a complete outer layer of longitudinal muscle; leading to loss of sacculations. There are also no appendices epiploicae in the rectum.

The rectum proceeds downwards and backwards as the anal canal 2–3 cm in front of the coccyx. The anorectal junction is slung forwards by the loop of the puborectalis, which merges with the top of the external anal sphincter, forming a palpable ledge (the anorectal ring) on per rectal examination. Hence the posterior wall of the rectum appears to make a right-angle at the anorectal junction. This angle widens during defecation as the puborectalis muscle sling relaxes to allow faeces to enter the anal canal.

Although the rectum has no mesentery, the connective tissue and fat around the rectum is now referred to by surgeons as the mesorectum. The visceral fascia surrounding the mesorectum is the *mesorectal fascia*. The mesorectum is bulkier posteriorly, where it also tends to be grooved in the midline. It contains the superior rectal artery and its branches, the

superior rectal vein and its tributaries, lymphatic vessels and nodes. A relatively avascular areolar tissue plane lies in between the mesorectal fascia and the parietal pelvic fascia; this forms the plane of surgical dissection in total mesorectal excision of the rectum for carcinoma. The plane is found to be most evident posteriorly and is only minimal laterally where the inferior hypogastric plexus lies tangentially on the surface of the mesorectal fascia. Crossing this interface of areolar tissue are autonomic nerve fibres from the plexus to the rectum and occasional small middle rectal vessels. The 'lateral ligament' of the rectum is found during surgery by defining surrounding connective tissue from the mesorectum; It is not seen on MRI or CT scanning.

Peritoneum covers the upper third of the rectum at the front and laterally, the middle third only at the front; the lower third is free of peritoneum which is reflected forwards on to the upper part of the bladder (in the male) or upper vagina to form the rectovesical pouch or rectouterine pouch (of Douglas). These pouches form the lowest parts of the peritoneal cavity. They are 7.5 and 5.5 cm from the anal margins in the male and female respectively and within reach of the fingertip on rectal examination. They are normally filled by coils of small intestine or sigmoid colon.

Anterior to the rectovesical pouch is the uppermost part of the base of the bladder and the tops of the seminal vesicles. Below the level of the pouch are the rest of the bladder base and seminal vesicles, the prostate, and the ends of each ureter and vas deferens. Between these structures and the rectum, a condensation of fascia forms a *rectogenital septum*—the *rectovesical fascia* of Denonvilliers. It is connected to the floor of the rectovesical pouch above and to the apex of the prostate below. In the fetus the rectovesical pouch extends to a lower level than in the adult, but gradual fusion of the anterior and posterior walls of the pouch accounts for the origin of this septum. The rectovesical fascia of Denonvilliers has a distinct whitish appearance, is closer to the rectum than to the prostate and is usually removed in rectal excision for carcinoma.

In females, in front of the rectouterine pouch is the uppermost part of the vagina (the fornix, with the cervix of the uterus), while below the peritoneal reflexion is the rest of the vagina, with the rectogenital septum intervening. This thin rectovaginal fascia fuses with the perineal body below.

Blood supply

Blood Supply is derived principally from the superior rectal artery, with contributions from the middle rectal, inferior rectal and median sacral vessels. The inferior mesenteric artery enters the sigmoid mesocolon and changes its name to superior rectal on crossing the pelvic brim. It crosses the left common iliac vessels medially to the ureter and descends in the base of the medial limb of the mesocolon. At the level of S3 vertebra (where the rectum begins) it divides into two branches which descend on either side of the rectum and subdivide into smaller branches. These vessels pierce the rectum and supply the whole thickness of the rectal wall. They continue submucosally into the anal canal, where they form a porto-systemic anastomosis with branches of the inferior rectal artery. The middle rectal arteries are present in only one in five people; they are small and supply only the muscle of the mid and lower rectum. The inferior rectal arteries are capable of supplying the rectum from below to the level of the peritoneal reflection from its anterior surface. The median sacral artery makes a small contribution posteriorly in the region of the anorectal junction, but its main interest is that it may cause bleeding at operations in this region.

The veins correspond to the arteries, but anastomose freely with one another, forming an *internal rectal plexus* in the submucosa and an *external rectal plexus* outside the muscular wall. Haemorrhoids are formed by the lower end of the internal venous plexus which continues with the vascular cushions of the anal canal. The main route of rectal venous drainage is via the superior rectal vein to the inferior mesenteric vein, which crosses the pelvic brim between the inferior mesenteric artery and the ureter. The inferior rectal veins drain to the internal pudendal veins.

Lymph drainage

Lymphatic drainage from the rectum is mainly upwards. Lymphoid follicles in the mucous membrane drain to epicolic nodes on the surface of the rectum and to pararectal nodes in the mesorectum. The upward drainage is via nodes along the inferior mesenteric artery to preaortic nodes. There is minimal lymphatic drainage from the lower rectum to internal iliac nodes along middle rectal and inferior rectal arteries, and along the median sacral artery to nodes in the hollow of the sacrum, and is unlikely to be a route for the metastatic spread of cancer if it has not breached the mesorectal fascia.

Nerve supply

The *sympathetic* supply is derived from fibres that accompany the inferior mesenteric and superior rectal arteries from the inferior meseneteric plexus. The *parasympathetic* supply is from S2, 3 and 4 by the pelvic splanchnic nerves via the inferior hypogastric plexus; they are motor to rectal muscle. The sensation of distension is conveyed by parasympathetic afferents. Similar to the bladder, pain fibres appear to accompany both sympathetic and parasympathetic fibres.

Rectal examination

The structures that can be palpated through the anal canal in both sex include the coccyx and sacrum behind, and the ischial spines at the sides. The anorectal ring felt posteriorly at the anorectal junction is a shelf-like projection over which the tip of the finger can be hooked when the patient bears down. In the male the prostate can be felt (but normal seminal vesicles are not usually palpable). In the female the cervix can be felt through the vaginal wall, with the uterosacral ligaments laterally and sometimes the ovaries.

Development

The rectum and the anal canal are derived from the dorsal part of the cloaca and the proctodeum. The anal membrane breaks down, at a site represented by the pectinate line in the anal canal; the anal valves are said to indicate the remains of the membrane. The part of the anal canal continuous with the rectum above the pectinate line is endodermal, and the part below which is derived from the proctodeum is ectodermal, hence the difference in the blood supply, nerve supply and lymph drainage of the upper and lower parts of the canal

TECHNIQUE

A therapist in enterostomas should mark the possible sites for stoma placement with patient in sitting, standing and supine postures before the patient enters the theatre. A Foley catheter is inserted, the patient is placed in the required position, namely the modified-lithotomy position, and the rectum is irrigated with both a solution with tumoricidal action such as povidone iodine and saline. If indicated ureteral stents are placed. In the hands of experienced laparoscopic surgeons, studies have shown that the surgery can be performed laparoscopically as well[31,32]; the same principles adhere whether the surgery is minimally invasive or open.

The intention of the procedure is complete resection of the malignancy along with a total pararectal lymph node excision which lies within the mesorectum. Additional lymph nodes may be present depending on the stage of the tumor, and they should also be dealt with. In oncologic proctectomy one overarching principle is that sharp dissection must always be performed. Sharp dissection is part of a meticulous and exact approach which avoids mesorectal disruption and in the process iatrogenic spread of the tumor. It also prevents inadvertent injury to the patient by identifying every important adjacent structure.

With this approach less blood loss is seen. Distraction bluntly leads to haphazard circumferential margins, and imprecise distraction compromises the extent of resection.

To reach the goal of complete resection with adequate radial and circumferential margins, the lateral extent of dissection must not breech the fascia propria of the rectum. Sharp dissection through Denonvilliers' and Waldeyer's fascia is included. To ensure an adequate distal margin, the rectum must also be mobilized anteriorly and posteriorly.

A generous midline incision is made. The peritoneal cavity is entered. Presence of secondaries is explored including liver palpation bimanually. Then the question of the primary cancer operability in the pelvis is also assessed. If there is no evidence of secondaries or an unresectable rectal cancer, the surgery is proceeded. Attention is turned to the left lateral attachments of the colon. The embryonic plane between the colon and retroperitoneum is entered by making an incision along the white line of Toldt (lateral peritoneal reflection). There are no blood vessels here. Upward traction is given on the left colon, along with lateral traction on the retroperitoneal tissues, and plane is developed with sharp dissection. The first step is the identification of the left ureter, which is swept laterally. The procedure of mobilization is continued toward the midline until we have reached the periaortic tissues. Now, we

look to mobilize the splenic flexure. The distal half of the transverse mesocolon is separated from the omentum by entering the lesser sac. The dissection is proceeded down to the base of the mesentery. Likewise, the phrenocolic and splenocolic ligaments are divided completely by extending the lateral dissection cephalad and around the spleen. The left colon now comes to lie in the midline as it is completely mobilized. Now, we can identify the origin of the inferior mesenteric artery (IMA) from the aorta. Again confirmation of the position of the left ureter is done as it is extremely vulnerable here. The IMA is then divided and ligated to allow for mobilization of the descending colon. Care is taken to preserve the small nerve fibers of the preaortic sympathetic/superior hypogastric plexus. This is possible by keeping the plane of dissection between the IMA and aorta flush with the posterior wall of the artery. At this level the inferior mesenteric vein is also divided. Next, the short left colic artery is identified and isolated. It is divided and ligated such that the marginal artery communication between the ascending and descending branches is still maintained. This ensures good collateral blood supply to the anastomosis or to the colostomy from the middle colic artery. Dissection is then carried up to the edge of the distal descending colon. Here, the division of marginal artery is carried out. Ligation of the artery is done if brisk arterial

bleeding is encountered. The descending colon is then divided between bowel clamps. When a coloanal anastomosis is planned, as a lengthening procedure, the inferior mesenteric vein can be ligated a second time, just below the pancreas, preserving the marginal artery.

The pelvic phase of the operation is then begun with the posterior dissection.. The plane immediately posterior to the IMA in the midline is developed sharply, which is carried down over the sacral promontory and into the pelvis. This must proceed between the presacral fascia and the investing fascia of the mesorectum in order to preserve the hypogastric nerves. Once they are identified, they have been swept laterally out of harm's way. The lateral attachments are divided sharply, close to the pelvic sidewall with the tissues held on stretch between the blades of a Kelly clamp using electrocautery. Now, the anterior dissection is begun. The peritoneal reflection between the lower uterus or bladder and the anterior wall of the rectum is incised. For tumors located on the anterior wall of the rectum, the peritoneum should be incised anterior to the reflection in order to preserve a fascial boundary around the tumor. This will lead into the plane of dissection between either the vagina or seminal vesicles/prostate gland and Denonvilliers' fascia. It is important to note that the parasympathetic nerves lie anterior to the Denonvilliers fascia. Hence there is an increased incidence of

injury to the nerves in this region by developing a plane anterior to the Denonvilliers fascia. For posterior tumors, nerve injury is minimized by developing the plane of dissection posterior to the peritoneal reflection between the Denonvilliers fascia and anterior rectal wall. Care is taken to mobilize the rectum distal to the tumor. In Low Anterior Resection, the rectum is then divided and the creation of anastomosis is done.

The neurovascular bundles lie anterolateral to Denonvilliers fascia and among other structures supply the seminal vesicles. Heald[33] advised a U-shaped incision to be made though Denonvilliers fascia to avoid damage to the neurovascular bundles. By avoiding nerve injury, the function of the genitalia is preserved. As demonstrated by Lindsey et al,[34] Denonvilliers' fascia lies just anterior to the fascia propria. Between the two lies the proper plane of dissection. It is more closely applied to the prostate than the rectum. Postoperative sexual dysfunction can be minimized by not excising Denonvilliers' fascia but without compromising the oncologic outcome of the surgery.

The necessity of extending the dissection to the levators for rectosigmoid and high rectal cancers, have been questioned by some[35]. Studies into this have been made by Adrian and Long[35]. They opine that wide resection of the affected portion of the mesorectum provides comparable oncologic results with adequate distal and radial margins of

5 cm and > 1 mm, respectively. Devascularization of the rectum distal to the anastomosis may be avoided by not resecting all of the mesorectum. A relatively low anastomotic leak rate of 7.3% has been achieved using this technique by Adrian and Long[35] .

If the case of APR, division of rectum is not necessary distal to the cancer. Instead, a metal ring is used to tag the sigmoid colon and left in situ. A Drainage tube is brought out through the lower abdominal wall. The dead space of the pelvis is filled up with omentum to exclude the small bowel and prevent bowel obstruction post-operatively. The abdomen is then closed and the end-descending colostomy matured.

Now the perineal phase of the surgery begins. A prone jack-knife or lithotomy position is employed. Closure of the anus is done with a purse-string suture to prevent extrusion of shed tumor cells. A diamond-shaped skin incision is made around the anus using the midpoint of the perineal body, both ischial tuberosities and the tip of the coccyx as landmarks. The avascular plane between the sphincters and the perirectal fat is followed and the incision is deepened into the ischiorectal fossa. Posterior division of the levators is done first under the coccyx and then the lateral division is done. The peritoneal cavity is reached and the metal ring previously placed in the presacral space is then retrieved. Through the posterior perineal wound, the proximal end of the specimen

is brought out. In a retrograde fashion and under direct vision the anterior dissection is completed. This minimizes the risk of injuring the distal ureters, prostate gland, or urethra and provides excellent exposure. Risk of violating the tumor is also minimized. Once removal of the specimen is done, the deep tissues of the perineal wound are irrigated. It is closed with interrupted 0-vicryl figure-of-eight sutures. Finally, closure of skin is done with vertical mattress stitches of 3–0 vicryl loosely approximated.

VARIATIONS FOR TUMOR LOCATIONS

For a midrectal cancer the distal resection margin is the distal edge of the mesorectum, at least 2 cm below the tumour.

For a distal rectal cancer the distal resection margin is the bared rectal tube 1 cm below the tumour.[12]

For a distal rectal cancer not invading the sphincters, dissection into the intersphincteric plane is sometimes needed to acquire a 1 cm distal margin. This dissection extends into the plane of the bared rectal tube beneath Waldeyer's fascia and within the upper external anal sphincter formed by the puborectalis sling. In females, who have a short

anal canal, the anterior circular fibres of the external sphincter may be revealed with further dissection in the anterior intersphincteric plane.

Distal rectal cancer invading the sphincters can be assessed with MRI, endorectal ultrasound and clinical examination under anesthesia. In such cases, Waldeyer's fascia covering the anorectal junction should not be incised to expose the bared distal rectal tube. Instead, an abdominoperineal resection is performed by taking a cuff of puborectalis and it’s covering endopelvic parietal fascia, resected as the circumferential margin of the anorectal junction *en bloc* with ischiorectal fossa fat, external sphincters and perianal skin (TME plus APR). On occasion when there is minimal invasion of the puborectalis, a clear distal margin can be taken by resecting the puborectalis while sparing the distal half of the anal canal and the external anal sphincter.

An anterior tumour location is worrying for at least three reasons, first because of the adjacency of the anterior viscera and thinness of the anterior mesorectum. Clinical examination under anesthesia, endorectal ultrasound and MRI are useful to determine whether there is an anterior fat plane that will permit an anterior resection margin thick enough to test negative. If tumour invades the anterior viscera, *en bloc* resection is required for curative resection: TME plus *en bloc* partial or complete resection of anterior viscera such as posterior wall of the vagina or

possibly pelvic exenteration for *en bloc* resection of rectal cancer invading the bladder, seminal vesicle and prostate.

A second concern with anterior location of a tumour is an increased risk of "fracturing" of the tumour during dissection. Particular care is needed to avoid tearing and fracturing of the anterior mesorectal fascia for an anteriorly located tumour.

A third worry is that the terminal genitourinary parasympathetic and sympathetic nerve branches residing in the prostate can be injured during dissection of the anterior mesorectum, particularly if the posterior prostatic capsule is breached (especially at the posterolateral capsule).

Consideration should be given to spillage of tumour cells during a distal resection. Many clinical and experimental reports show that viable tumour cells can be found in the lumen of the rectum and anal canal distal to the tumour. To minimize the potential for implantation of these intraluminal cancer cells that could potentially cause recurrent cancer, Moran and colleagues[13] have advocated the placement of 2 sequential clamps or staple lines with interval intraluminal washout using a tumouricidal solution. The first clamp or staple line is placed distal to the tumour. The anorectum is irrigated with a tumouricidal or antiseptic solution such as water, betadine or chlorhexidine. After the intraluminal

washout, the second clamp or staple line is then placed on the true distal resection margin, thus avoiding implantation of intraluminal cancer cells.

SPHINCTER PRESERVATION OR ABDOMINOPERINEAL RESECTION?

The purpose of any oncologic Surgery remains survival and prevention of recurrence. But the outcome is not influenced by surgical technique alone, but by various other predetermined factors such as cancer's stage and biological behaviour of the tumor. Through proper surgical technique and selection of appropriate surgery, minimal local recurrence is possible. If it is possible to provide adequate margin, then the surgeon can next consider the possibility of a sphincter preserving resection. Though much debate exists as to for which patients sphincter preservation can be done, there is clear consensus as to the contra-indications to sphincter preservation. First, it should be determined if the tumor involves the anal sphincter. No Attempt at sphincter preservation is attempted if the tumor involves the anal sphincter. Next, the function of the anal sphincter is assessed. An anastomosis with an incontinent anal sphincter would be less functional than a Colostomy. Finally, in

very obese patients in whom the safe creation of an anastomosis cannot be guaranteed, sphincter preservation is not undertaken.

Preoperative evaluation of the patient is done, which includes a thorough history, physical examination with particular emphasis on anorectal examination which includes a digital rectal examination and rigid Proctoscopy. The precise distance of the tumor from the anal verge can be measured with rigid Proctoscopy. TransRectal Ultrasound is next done to further delineate the size of the malignancy, depth of invasion, nodal status and infiltration of surrounding structures. It has an accuracy of 80 to 95% in assessing the T stage compared to CT with 60 to 75% or MRI 75 to 85%. Hence TRUS is preferred. A coloanal anatomosis is considered only if there is separation between the cancer and the sphincter. If the tumor is fixed to the pelvic floor, or the tumor involves the sphincter, an APR is undertaken. TRUS also provides 70 to 75% accuracy in determining presence of lymphadenopathy but is inaccurate in revealing the architecture of the lymph nodes. Involvement of vagina in women and prostate or seminal vesicles in men is not an absolute contra-indication to restorative surgery, but excision of tumor with clear margins is essential.

Sphincter-preserving surgery is still not accepted as a valid treatment modality for rectal cancer due to the consideration that APR

offers the maximum radial and distal margins. The correlation of tumor free margin has been studied and documented by the Radiotherapy+TME trial in the Netherlands. They included 656 patients in their study and found >2mm margins conferred a local recurrence risk of 5.8% while radial margins <2 mm were associated with local recurrence of 16%. Distant metastasis was 12.7% with margins >1mm and 36.7% for margins < 1mm which was associated with shorter survival. The optimum distal margin has been studied by Paty et al[20] and Vernava and Moran,[21] after the popularization of TME, who have conclusively proven that a 2 cm margin is not an accurate delineation for optimal surgery. Indeed, many studies have shown that distal infiltration of cells is rarely greater than 1 cm.,[22,23,24] but distal margins ≤8 mm have shown increased anastomotic recurrence and reduced survival. Hence, if tumor free margin of 1 cm cannot be given from the sphincter, then to avoid leaving any residual disease behind, an APR must be done.

Patients with incontinence should have an abdominoperineal resection (APR). They will be better adjusted to management of the Colostomy than with incontinence caused by anastomosis distally. Patients often have incorrect preconceived notions about stomal limitations, which can be alleviated by speaking with an enterostomal therapist. This also improves patient's expectation of surgery

postoperatively.[25] If a coloanal anastomosis has been performed, bowel function will be altered for many months. Increased frequency and loose stools are seen more than 5 times a day. This can further worsen over time and with post-operative radiotherapy. In some cases, this can be partially mitigated by performing a coloplasty or a pouch. Also required is a dietary change with increased fiber. A supporting role is offered by anti-motility drugs. It is important to educate the patient on the surgery and the patient to have realistic expectations about it.

ASSESSMENT OF TME SPECIMEN

TME is said to be ‘Complete’ if the Mesorectum is intact and smooth, defects are not deeper than 5 mm , there is no coning, and the CRM is smooth and regular. It is said to be ‘Nearly Complete’ it mesorectum is of moderate bulk and irregular, defects extended more than 5 mm but the muscularis propria is’t seen, coning is moderate and CRM is irregular. Finally, it is said to be ‘Incomplete’ if mesorectum shows little bulk, defects are extending beyond muscularis propria, marked coning is seen and CRM irregularity is present.

In general, markers of successful surgery are if surface is smooth and without tearing or incisions. If Partial Mesorectal Excision is done, the transection plane should be perpendicular to the rectal wall, and coning must not occur. Coning is a phenomenon which happens during LAR and APR. The surgeon tends to cut towards the tubular rectum while dissecting distally, rather than staying outside the facial plane of the rectum, namely the visceral mesorectal fascia. A tapered, conical appearance is given to the specimen due to this. It is thus a marker of suboptimal quality of the surgery.[5]

The circumferential radial margin (CRM) is another term that is applicable for rectal tumours. In the rectum, a bare non-peritonealised

area is located both anteriorly and posteriorly, though not symmetrically. The anterior CRM is located below the lowest point of rectal serosa only in the most distal aspect of the specimen. The triangularly shaped posterior CRM runs throughout up to the start of the sigmoid mesocolon. Definition of a positive Circumferential Radial Margin is a direct tumour extension (which can be either continuous or discontinuous) or a lymph node positive within 1 mm of the non-peritonealised, radial soft tissue edge.[6]

British guidelines for the examination of resection specimens of rectal malignanacy include the presence or absence of perforation, degree of coning in distal portions, surgical defects and the assessment of contour for bulk. The Royal College of Pathologists, United Kingdom recommend leaving, the bowel intact during fixation. This is done so that the fixed specimen can be serially sliced and the CRM can be preserved. If the specimen is opened, their assessment would be compromised.[7]

The Working Group of German Cancer Centres and the German Cancer Society require an initial assessment done macroscopically. This involves documentation of the extent of mesorectal excision (ie TME vs PME), of the quality of mesorectal excision as well as coning and specimen surface quality, and in the event of PME, distance between distal transection and distal tumour edge; these features are classified as

smooth and intact or, local well defined defect (less than 5 mm vs greater than 5 mm), or marked extensive defect (visible muscularis propria layer), or tearing/ incision of tumour. Another recently described method is stain marking which is done to detect small tears in the mesorectum. Ink or methylene blue solution is injected into the specimen postoperatively via the superior rectal artery or IMA. While with optimal TME, no leakage is seen; defects in the mesorectal fascia show leakages.[9]

Circumferential radial margin (CRM)

In patients with rectal malignancy, in terms of predicting the risk of local recurrence, the single most important factor is accurate determination of CRM. The term positive margin is given for both direct extension of the tumour and the positive lymph nodes present within 1 mm of the CRM. However, certain studies have shown that all positive CRMs do not uniformly impact the risk of recurrence in the same way. This was demonstrated by Nagtegaal *et al*. He showed that when a positive CR Margin was due to direct tumour extension, they developed more frequent local recurrence (22.1% vs 12.4%, $p = 0.06$) than those with a positive CR Margin was due to positive nodes; Their study went on to state that in fact, no difference existed in local recurrence rate

between patients with a negative CRM and those with positive nodes-positive CR Margin.[16]

It also appears that a relationship existed between the quality of the mesorectum and the risk of having a positive CR Margin. Patients with a tumour extension - positive CRM had a more frequent incidence of an incomplete mesorectal excision compared to those who had a CR Margin negative (44% versus 24%, at $p<0.05$). So patients with direct tumor extension were more likely to have incomplete excision of the mesorectum; interestingly, such a difference was not observed in the quality of the mesorectum among patients with a positive nodes - positive CRM[16].

Thus, a positive radial margin is a margin of less than or equal to 1mm. Most studies have conclusively shown that increased risk of local recurrence exists with tumours within 1 mm of the CR Margin. Wibe *et al*, using Norwegian Cancer Registry (n = 686) data showed that patients with a less than 1 mm margin had a 22% local recurrence rate. This was in comparison to patients with a negative CR Margin who had a 5% local recurrence rate.[18] Additionally, increased risk of distant metastases was seen with less than 1 mm radial margins (37% versus 15% radial margins >1 mm patients) and shorter duration of long term survival (70% versus 90% at 2 years for patients with radial margins greater than

1 mm).[8] However, Nagtegaal *et al* have extended this margin to 2mm and shown that patients with a margin less than or equal to 2mm had a 16% risk of local recurrence while those with a margin greater than 2 mm had a 6% risk of local recurrence. [6]

Important prognostic implications are also due to the location of tumour within the mesorectum, since the amount of soft tissue between the CRM and the tubular rectum varies circumferentially. To determine if tumour location was related to outcome, 401 patients with rectal cancer were retrospectively analysed by Lee *et al* who underwent TME procedures. Only males were included in the study as for females, complete pelvic exenterations was done in greater frequency. They found an increased rate of local recurrence and death in stage matched males, with anterior tumours.[19] This result is mostly due to the region between the CRM and the anterior rectal wall have relatively lesser amount of soft tissue.

Also, it was discovered that the risk of local recurrence increases, the lower the cancer is in the rectum. It is not known as to whether this is due to tumour biology of low rectal cancers or due to the greater frequency of APRs performed in such patients. Quirke and other Dutch TME study investigators have shown that APR with TME is more often associated with poorer prognosis, due to an increased frequency of CRM

involvement and a poorer quality of mesorectum, compared to LAR + TME procedures.[20] This was contradicted in a study by Faerden *et al*. He studied 140 patients prospectively. They had rectal cancer and underwent TME. A higher rate of local recurrence was seen in patients with tumours less than 6 cm from the anal verge compared to those where the distance was more than 6 cm (18% versus 5%, where p = 0.0014); however, with respect to abdominoperineal resection, no difference in the frequency was seen between these groups.[4] As such many factors may influence the low rectal cancers having aggressive behaviour, but regardless of the surgical technique, the thin envelope of the lowermost portion of the rectum and low volume of distal mesorectal soft tissue are contributory factors.

Lymph nodes

Overall survival is influenced by systemic spread than by local recurrence. Therefore, the single most important determinant becomes Lymph node status in terms of overall survival. The five-year survival with positive nodes is 40% which is significantly lower than those with negative nodes (68%).[8] Many studies have not compared both TME and lymph node status consistently, thus with some claiming that lymph node positivity has a similar impact to local recurrence as CRM

positivity. The Heald led Colorectal Research Unit from Basingstoke, UK in order to combat such claims, recently published data from 170 patients who underwent TM Excision for rectal malignancy.[3] As expected patients with positive lymph nodes had a higher local recurrence rate compared to negative node patients, but the recurrence in positive node patients was only 7.5%; Thus with adequate excision of the mesorectum a remarkably low recurrence rate can be attained even for node positive rectal cancer.

How many nodes should by examined to classify a patient as N0. The current TNM guidelines declare that a minimum of 12 nodes should be examined but these are based on studies that did not consistently employ TME.[26] A possible ideal number of nodes was suggested in a study by Wang *et al* . They microscopically examined whole-mount sections of 5mm serially sliced mesorectums.[17] In their study, 18 specimens were examined with 992 lymph nodes, on average 32 per rectum and metastases was contained in 148 (15%) of these. Interestingly, a majority of the total number (922 /93%) and a majority of the positive lymph nodes(104 70%) were less than 5 mm in diameter. As demonstrated in recent results of the Dutch TME trial, even 12 nodes

retrieval is difficult to achieve in practice. Less than 12 nodes were available for examination in 82% of node negative patients.[27] But, the surgeon must be encouraged to find more nodes as several studies support the fact that this will improve the staging. Two studies were done by Caplin *et al* and Tepper *et al* in this regard. The first study showed that node positive patients had a similar prognosis as node negative patients with less than 7 nodes examined. The second study showed that patients with greater than 14 nodes harvested had a better disease free survival than patients with less than 8 nodes harvested[28,29] . Plus if the minimum number of nodes to be harvested is set as 12, then it will lead to under-staging as after finding twelve nodes, the procedure will be abandoned. Also, the more distant nodes may be harvested, losing the closer to rectal wall and more proximal nodes.

The most important factors in determining the harvested number of nodes are enthusiasm of the examiner, extent of examination, routine visual inspection, palpation and dissection. Adjuncts helpful to identification of lymph nodes are fat stretching, xylene clearance, ether-based methods, and wintergreen oil/cedar oil clearance.[30,31,32,33,34]

In fact, the Cancer Committee of the College of American Pathologists advised the use of "visual enhancement techniques" if with traditional methods, less than 12 nodes are found.[10] Special equipment is needed for most of the above-mentioned methods, the use of volatile, noxious compounds or upto 3 weeks treatment of pericolic fat. Another technique was the usage of GEWF solution which was successfully used by Newell *et al*. It is a non-noxious solution, which within 24 hours gives good yield of lymph nodes.[35]

REVIEW OF LITERATURE

Heald and colleagues[36] conducted the first large case series at North Hamphsire Hospital in Basingstoke, England, reviewing their experience with TME. It consisted of 519 patients over a 20 year period from 1978 to 1997. All patients had adenocarcinoma of the rectum proven histologically. The tumors were located up to a distance of 15 cm from the anal verge. Dr. Heald standardized the surgical approach by performing all the surgeries himself. All surgeries were taken into consideration, that is both the surgeries with palliative and curative intent. Forty-nine of the 519 patients received preoperative radiation therapy. The performed surgeries were Low Anterior Resection- 465, Abdomino-perineal Resection-37, Hartman procedures - 10, local excisions -4, and laparotomy and closure in 3 surgeries as it was discovered to have unresectable disease. The stage wise distribution was: Dukes A – 102 patients, Dukes B -167 patients, Dukes C - 142 patients, and Dukes D -108 patients indicating metastatic disease or residual disease. 382 patients received a diverting stoma and within 2 months, they were closed. To record the information, a database was created. Follow-up was lost on 1 patient. All other patients were regular in their follow-up in their postoperative period.

Following LAR, the 10-year survival rate was 80% and the5-year survival rate was 81%. Here, local recurrence rates were not affected by the location of the anastomosis, location of the tumor, anastomotic leak rates, tumor grade or Dukes stage, but by extramural vascular invasion.

Coming to survival, it was 66% at 10 years and 68% at 5 years. But in those treated with aggressive surgery, the survival was 78% at 10 years and 80% at 5-years. Coming to local recurrence rates, at 10 years it was 8% and at 5 years it was 6%. With LAR, the local recurrence was 5% at 5 and 10 years. In comparison, in the APR patients local recurrence was seen at 36% at 10 yrs and 17% at 5 yrs ($p\ value < 0.001$). Among the patients with distant metastases, none were surviving beyond 5 years. In LAR, the leak rate was 6.5% which was clinically apparent, but another 5.5% of patients had silent but radiologically detected leaks.

Only in a small percentage of their patients, adjuvant therapy was used and therefore could not be included in analysis. Although more trials involving impact of adjuvant therapy and TME are now available, Heald concluded that that with a properly performed TME, chemo-radiotherapy might not be necessary. But, those patients undergoing APR had uninspiring cure rates. Patients undergoing anterior resection were the only ones whose outcomes were improved by TME. It was suggested during the perineal portion of the surgery, tumor could have

implanted. Also, the low rectal cancers have a thin fascial envelope which in some is absent for 1-2 cm, hence, the cancer can infiltrate faster into surrounding structures.

The Hong Kong Queen Mary published 622 patients who were operated with LAR. Those with lower two-thirds rectal malignancy were treated with TME; upper rectal and rectosigmoid malignancies were treated with a partial mesorectal excision or a cancer-specific PME, where the transaction of the rectum was done about 4 to 5 cm below the tumor. Eight cm from the anal verge was the median level of the cancer in this series. 90.5% of patients received surgery with curative intent (positive margins was seen in 3 patients), with palliative procedure being done in the rest. 83.1% of patients had a stapled anastomosis. The rest had a hand-sewn anastomosis, 73 were high colorectal anastomoses and 32 were coloanal. 42 patients received radiation therapy, and neo-adjuvant radiotherapy was given to half of them. 0.8% belonged to stage 0, 16.1% to stage I, 36.7% to stage II, 38.4% belonged to stage III, and 8.5% to stage IV.

Partial Mesorectal Excision was done in 226 patients and TME was performed in 396 patients. The problems with TM Excision were higher blood loss, higher incidence of stoma formation, longer operative times and longer hospital stays. TME was also associated with a higher

rate of anastomotic leaks (8.1%) when compared with PME (1.3%). Furthermore, independent risk factors for anastomotic leaks as found by multivariate analysis were TME, blood loss > 500 mL, the absence of a stoma and male gender. Yet, between patients undergoing TME or PME, no significant difference was seen in the overall postoperative mortality (1.8%) and morbidity. Univariate analysis showed significant factors predicting local recurrence were creation of a coloanal anastomosis, stage of disease, perineural or lymphovascular invasion and a distal margin of less than 2 cm. However, multivariate analysis showed high rates of local recurrence to be associated with only the presence of a coloanal anastomosis and the stage of disease. Actuarial 5-year and 2-year distant and local recurrence rates were 9.7% and 6.0%.

39.6 months was the median follow-up for the patients. In all patients studied, 74.5% was the 5-year cancer specific survival. Tumor stage and the presence or absence of perineural invasion and lymphovascular invasion were shown by multivariate analysis to predict disease-specific survival. The authors, based on their findings advised the use of TME only in limited cases due to higher incidence of stoma formation, a more technically demanding surgery, higher anastomotic leak rates, and longer operative times. By demonstrating similar cancer-

specific survival patterns between TME and PME, they have argued that oncologic outcome is not altered with this approach.

Such superior local control has been produced with TM Excision that some have questioned the need for neo-adjuvant therapy for prevention of local recurrence. The Dutch Colorectal Cancer Group investigated the efficacy of TME for rectal cancer with preoperative radiotherapy in a landmark study[38] . Patients without evidence of distant metastases and with histologically confirmed adenocarcinoma within 15 cm of the anal verge were enrolled over the 3-year period. Exclusion criteria were patients initially treated with local excision and patients with fixed tumors, as were patients with coexisting or previous cancers. Additionally, patients who had undergone prior pelvic chemotherapy, or radiotherapy or prior large bowel surgery, were also excluded. Randomization was done and patients were assigned to TME alone or preoperative radiotherapy and TME. Radiotherapy was given for 5 days, daily for 5 Gy followed by TME. Follow-up was done every 3 monthly in the first year and then once yearly for 2 years. Surveillance involved imaging of the liver with CT and endoscopic investigation. Of the 1861 patients who were included, 937 fell in the surgery alone group and 924 patients were assigned to the pre-operative radiotherapy and surgery

group. There were similar numbers of LARs, APRs and Hartman procedures between the two arms of the study.

The average period between randomization and surgery was 14 days in the surgery alone group and 21 days in the radiation group, the extra days accounting for the days spent on radiotherapy. The surgery alone group had a statistically significant ($p < 0.001$) lesser amount of blood loss (900 mL) compared to the radiation group (1000 mL). Perineal complications were also increased with radiation therapy compared with the surgery alone group (26 vs 18%, $p = 0.05$). 87 patients developed local recurrence, of whom 32% had both local and distant disease and 52% had an isolated local recurrence. 16% had distant metastasis followed by local failure. The local recurrence rate was 8.2% in the surgery alone group and 2.4% in the radiation group ($p < 0.001$). Multivariate regression analysis was done, independent risk factors for local recurrence were TNM staging ($p < 0.001$), tumor location ($p = 0.03$), and treatment group assignment ($p < 0.001$), but surgical procedure ($p = 0.90$) was not found to be statistically significant. Additionally, univariate analysis showed that the use of preoperative radiotherapy did not reduce the risk of local recurrence for cancers at other locations but it did reduce the risk in patients whose tumor was within 5 cm from the anal verge. Overall the surgery alone group had a

recurrence rate at the time of 2-year follow-up of 20.9% and the radiation arm had a recurrence rate of 16.1%. Stage II and III cancers had their recurrence rates reduced with preoperative radiotherapy, but stage I and IV cancers were not found to be influenced by it. Multivariate subgroup analysis showed no interdependence between treatment assignment or TNM staging or tumor location. Overall survival was the same in both groups, 81.8% in the surgery alone group and 82% in the radiation group ($p = 0.84$). The rate of distant disease was significantly different, 16.8% in the surgery alone group and 14.8% in the radiation group. At the end of the study period, the patients dead were 20%, 231 were cancer-related, 61 were postoperatively and 70 were deemed due to other causes. The findings of the Dutch study were that use of combination of preoperative radiotherapy and TME benefited local control of disease, but did not affect overall survival even though distant disease was found to be more common in the surgery alone group. The only disadvantage of radiotherapy was the higher intra-operative blood loss, but morbidity and mortality were not significantly increased in comparison with patients not receiving radiotherapy.

The efficacy between postoperative radiotherapy and neoadjuvant radiochemotherapy (RCT) was compared in a German trial CAO/ARO/AIO-94[39] . Here, all patients had locally advanced (T3/T4 or

node positive) disease and underwent TM Excision. Randomization of all the patients was done to pre- or postoperative RCT. The tumor and pelvic nodes were treated with a total dose of 50.4 Gy of radiation. Also, 5-Fluoro Uracil, as a 120-hour continuous infusion was given with radiotherapy at 1000 mg/m^2/d during the 1^{st} and 5^{th} weeks. In bolus form another 4 other cycles of 5-FU were given. In the postoperative radiotherapy group, a boost of 5.4 Gy of radiation was also given. In the preoperative RCT arm, 4 to 6 weeks after completion of preoperative RCT, patient underwent surgery, with 4 cycles of 5-FU given 3 to 4 weeks post surgery. Immediate surgery was done in the postoperative group with 5-fluoro uracil infusion comprising six cycles and started within 4 weeks.

From 26 different hospitals, 805 five patients were randomized. The adjuvant group had 363 patients and the neoadjuvant group had 355 patients. The most common side-effects were diarrhea, with 11% in the adjuvant group having grade 3 toxicity and 12% in the neoadjuvant group. Grade 3 erythema, nausea, or leukopenia was experienced by less than 3% of patients in either arm. Both groups had similar postoperative complication rates and no difference was seen in postoperative bleeding (3%) or anastomotic leaks (12%). Postoperative mortality between the two groups was also not found to be significantly different.

In a nutshell, several large prospective studies have shown that local recurrence is superiorly controlled with TME than with conventional surgical techniques. On the other hand, morbidity is also not significantly higher with TME over conventional surgery. With regard to neoadjuvant radiotherapy, TME appears to be additive to it, and has not been shown to be able to replace it completely from the present studies.

PROBLEMS AND CONROVERSIES

The disadvantages of TME appear to be threefold. They include a difficult distal pelvic dissection because of the attention required to preserve the pelvic autonomic nerves and to maintain an intact mesorectal fascial envelope. Dissection of the mid- and distal rectum distal to the cul-de-sac is technically more difficult because of the decreasing dimensions of the distal pelvis and access impedance by the anterior pelvic viscera. Rectal cancers within 10 cm of the anus have higher local recurrence rates associated with the increased rate of incomplete TME-resected specimens.[9,21]

Because the mesorectal excision is so complete and leaves a "bared" rectal tube distal to the distal edge of the mesorectum, a second difficulty is a difficult low colorectal or coloanal anastomosis. This low anastomosis has a leak rate of about 15%– 20%, which is substantially higher than the 5%–10% leak rate for intraperitoneal colorectal anastomoses.[16,17]

It is therefore prudent to construct a temporary defunctioning ileostomy or right transverse colostomy to protect the patient from severe sepsis in the event of anastomotic leakage. Once the low

anastomosis is proven to have healed, a subsequent surgery to close the defunctioning stoma will be required.

Despite the preservation of the anal sphincter, a third disadvantage is the loss of rectal reservoir function, resulting in increased frequency and urgency and decreased ability to delay defecation, with possible fecal incontinence. Injury to the anal sphincter from radiation therapy will worsen problems of incontinence.

Whether TME is needed for upper rectal cancer is controversial. TME removes all pararectal lymph nodes within the mesorectum, including lymph nodes distal to the cancer. Pathological examination of mesorectal specimens of upper rectal cancer have not shown metastases to lymph nodes in the mesorectum more than 5 cm distal to the cancer.[18,19,20]

Therefore a subtotal mesorectal excision with a distal 5-cm margin is likely sufficient to remove all pararectal lymph nodes with potential to contain metastases. In performing a subtotal mesorectal excision it is imperative to resect the distal mesorectal margin at right angles to the long axis of the rectum, so as not to leave behind lymph nodes with malignant potential; in other words, do not “cone” into the distal mesorectal resection margin.

Dissection distal to the cul-de-sac takes extra time and care. Although some surgeons dissect anteriorly early in the dissection of the midmesorectum, early posterior dissection to the pelvic floor greatly facilitates identification of the lateral stalks.

In some cases where dissection of the mid- and distal mesorectum is made more difficult by increased adherence (e.g., in cases of inflammation or fibrosis), moving the dissection from the right side to the left and vice versa may facilitate the dissection. If the progress of dissection is particularly slow at any point, sometimes leaving that area and dissecting in another area such as the contralateral side of the mesorectum will permit improved distraction of tissue planes upon return to dissection of the original area of non-progress.

IMPACT OF TME AND PROBLEMS WITH ANASTOMOTIC LEAKS

The Dutch Colorectal Group which was conducted in The Netherlands, did a comparative study[40] on outcomes from the Total Mesorectal Excision and rectal cancer trial conducted by them[38] with data from another trial, the older cancer recurrence and blood transfusion (CRAB) trial. In the CRAB trial, conducted before TME, much emphasis on standard surgical principles was not made. In both studies, surgery was the primary treatment modality and neoadjuvant radiotherapy had not been used. But, the two studies were not truly comparable. This study had more older female patients, and more cases of postoperative radiotherapy. But, they did not differ in terms of tumor stage, procedures done and tumor location. Higher incidence of anastomotic leaks in the TME group was shown by Univariate analysis, but on multi-variate analysis, a statistically significant difference was not seen. However, in the TME trial, local recurrence was improved (9 versus 16%). Also, whether the patient underwent conventional surgery or TME had a bearing on overall survival with ($p = 0.019$) a higher survival rate in the TME trial.

Law[41] reviewed 205 patients and reported similar findings in rectal cancer resections that were less than six cm from the anal verge. During the period of patient accrual, a reduction in the incidence of APRs was observed by the authors from 36 to 20%. In contrast, the APR group showed more five-year actuarial local recurrence (23.5%) than the group with double-stapled anastomoses (11.2%). Overall, the 5-year survival rate was 51.1% in the APR group while in the LAR group was 69.1%. But significance was not found. Anastomotic leak was experienced by only 6 patients.

Higher leak rates[42] with TME have been reported by some series, raising concerns that higher leak rates were the price of the improved oncologic results. Several explanations have been posed as to why this complication is more likely with TME. Difficulty was experienced in report reading as all the studies did not follow a common protocol. They differed in terms of leak definition, usage of pelvic DTs, anastomotic technique, whether a diverting stoma was used, and bowel preparation. Another study was done by Bruce et al[43] who reviewed 49 studies concerning anastomotic leaks. These 49 studies to diagnose an anastomotic leak used 29 different definitions. One important factor in implicated increase in leaks is that they are at risk for loss of vascularity of the anorectal stump due to the removal of the distal mesorectum and

the subsequent low-level of many of these anastomosest.[44] Low-lying anastomoses have been shown to be an independent risk factor for increased leakage risk by many studies[45,46,47] . Eriksen[48]studied this issue from 1993 to 1998 in 1958 patients undergoing LAR with TME. He found the incidence was 11.6% and it was more in anastomoses that were less than six cm from anal verge, in patients undergoing neoadjuvant radiotherapy and in men. The authors concluded that protection by a diverting stoma was necessary after creating a low anastomoses with TME.

However, the partial mesorectal excision (PME) which is a variation on TME mentioned by Law[37] was developed to control leak rates by excising a good amount of mesorectum and not the entire mesorectum lying distal to the tumour. The name partial implied removal of healthy margin according to tumour location. Law and others used the technique on more proximal malignancies of the rectum and found decreased leak rates. Several studies[49] have shown that the cancer spread distally for less than 3 cm. It is still not how much to leave behind distally, but for the malignancies that are more proximal; there has been a movement toward PME. One technical aspect is that of ‘coning’. Coning involves narrowing the circumferential margin of dissection producing a cone and not a cylinder of mesorectum, as it is performed

distally. If the surgeon “cones” the tissue, a lot of mesorectum will be left behind, and control of the cancer will be compromised. Further studies are required into PME. At present, PME is proven to lower leak rates statistically. A decrease in leak rate was also observed as the surgeon’s expertise with the technique increased. Carlsen's[42] illustrated this point in a group of 76 patients who underwent TME.

PROBLEMS WITH FUNCTIONAL OUTCOME

Increased incidence of urgency, fecal incontinence and bowel frequency is seen with TME.[50] Certain factors affected the function of the bowel postoperatively. The factors which had an impact are the level of the anastomoses, the type of anastomotic technique, the level of preoperative anorectal function, and whether they experienced an anastomotic leak. The factors which influenced due to surgical technique were sphincteric damage, a smaller rectal reservoir following proctectomy, and loss of pelvic nerves during sacral dissection leading to loss of sensation. Generally older patients were considered to have more functional problems and were a contra indication to low anterior resection, but it was not supported by a study done prospectively of 87 patients underwent TME and an anastomsis within 1 cm of the sphincter . Follow-up was done for an average of 24.1 months, were grouped as younger (≤65 yrs) and older (>65 yrs). No significant difference was seen in between the younger and older patients in terms of urgency or the number of bowel movements per day or continence. In other studies as well, similar results have been replicated.[53]

Kollmorgen and colleagues[54] demonstrated postoperative deterioration of anorectal function from use of adjuvant radiotherapy. They compared 59 patients who didn’t receive radiation therapy and 41

patients who were subject to radiation post-operatively. Increased stool frequency per day were seen in the radiotherapy group (7). The surgery alone group had less bowel movements (2). More number of incontinence (17% versus 0) and more of clustered bowel movements (42 vs 3%) were also seen in the radiotherapy and surgery group. More common were also liquid bowel movements in the radiated patients. This led to more perianal skin problems (41 versus 12%). Hence wide difference was seen in the function of the bowel before and after treatment between the two groups (93 and 61%).

Yamana et al[55] suggested that we can predict postoperative outcome by the use of measuring preoperative anorectal function. 32 patients who had a LAR were followed. Rectal sensory threshold, maximal tolerable rectal volume and anal mucosal electrosensitivity were decreased post-operatively. Yamana et al finally stated that patients who had a lower rectal sensory threshold, larger maximal tolerable rectal volume, and longer anal high-pressure zone had better postoperative anal function.

AUTONOMIC NERVE PRESERVATION AND IMPACT ON URINARY AND SEXUAL FUNCTION

In the postoperative period with good control of disease, well-preserved urologic and sexual function is possible. This is by the precise technique and sharp dissection of TME by sparing of the autonomic pelvic nerves during proctectomy. In contrast, the first descriptions of APR or LAR reports a male impotence rate nearing 100%.[56] A retrospective study was conducted by Havenga et al[57] on 129 patients who underwent a nerve-sparing TME based on a standardized questionnaire. Approximately 63% of female patients and 73% of male patients complained of no significant urinary symptoms after their procedure. The remainder complained of atleast 1 symptom such as incomplete bladder emptying, difficulty in bladder emptying, urinary leakage or dribbling or a feeling of urgency. Zero patients required long term catheterization. A higher incidence of these complaints was observed in those who received radiotherapy and underwent APR. 46% of older patients and 86% of patients under 60 yrs maintained normal sexual activity. Comparing LAR to APR, diminished sexual activity was not seen in 76% of LAR cases but only in 53% of APR patients. Erectile tumescence was seen in 67% of cases older than 60 and in 86% of cases under 60. Thirty three cases were younger who had LAR, and all of them

maintained spontaneous erection and their ability to engage in sexual intercourse. In about 40% of patients post-operatively, retrograde ejaculation was seen. Similarly good results were seen in female patients, with sexually activity maintained in 86% after surgery.

Similar results were reported by Shirouzu at al[58] . Over 20-yrs, he made a review of 403 patients who had undergone proctectomy, Only a few patients had a nerve-sparing dissection. The10-year disease-free survival rates and recurrence rates were neither increased nor decreased in the nerve preservation group, with only 2% lost to follow-up. In addition, in the nerve-sparing group, better preservation of urinary and sexual function was seen. In more than 80% of the nerve preserved patients, urinary function was preserved. In comparison, the other group had >90% of patients complaining of urinary disturbances. Likewise, 65% of the nerve-preserved patients had preserved ejaculation and 79% could maintain erection.

Kim and colleagues[59] studied 68 men and assessed erectile dysfunction and prostate symptoms by performing urinary flowmetry and using questionnaires. All 68 men had undergone TME with nerve preservation for rectal malignancy. The function before and after surgery was compared. Preservation of nerves also preserved the ability to

maintain urinary flow, void volumes, orgasmic function, sexual desire, antegrade ejaculation and erection.

NEOADJUVANT RADIOTHERAPY WITH TOTAL MESORECTAL EXCISION

Neo-adjuvant radiation therapy with surgery produces lower rates of recurrence when compared to surgery alone. But most of these reports used a non standardized approach for surgery. Hence, a very high rate of recurrence was seen in the non adjuvant[60] groups. The combination of Total Mesorectal Excision and pre-operative radiation therapy has lowered recurrence rates by at least 50%. Even with suboptimal resection, the use of both neoadjuvant chemo-radiotherapy and surgery improves survival. In the Swedish Rectal Cancer Trial,[61] preoperative radiation therapy a shorter course was given and local recurrence rates were reduced to 11% from 27%. It also increased 5-year survival to 58% from 48. But maximum benefit is seen when proper surgical technique is used with TME `and the survival benefit cannot be reproduced on any other setting. The Dutch Colorectal Cancer Group[38] using only the principles of TME achieved an 8.2% local recurrence rate in the only

surgery group. Preoperative radiation of 25 Gy was used which further reduced the rate of local recurrence to 2.4%. However equivalent 2 years survival was noted in the two groups. Currently focus is on selecting those patients in whom neoadjuvant therapy would by most useful such as those with serosal disease so that cost and complications are reduced while maximizing oncological benefit. Magnetic Resonance Imaging is used successfully to find out the involvement of the circumferential radial margin. These patients would benefit from neoadjuvant therapy.[62,63,64]

Another advantage of neoadjuvant radiation therapy is that the size of the tumor can be reduced and an APR can be avoided by increasing the distance from the sphincter and allowing sphincter-preservation. A permanent colostomy may be avoided; however, caution must be used when changing the surgery based on tumor response. Even after a complete response to neoadjuvant treatment, microscopic nests of malignant cells seen in upto 75% of patients.[65] Thus, the "melting" of the lesion does not change the true stage of the cancer. Keeping this in mind the surgeon must proceed with APR if the sphincter complex is involved.

Use of Short-term neoadjuvant radiotherapy (25 Gy over 5 to 7 days) had also led to increased sexual disturbance. It can also result in

decreased morbidity free life. Marijnen[66] and colleagues used the Rotterdam Symptom Checklist and studied the Quality of Life and sexual disturbance. A total of 990 patients who had undergone Total Mesorectal Excision were studied after randomization to either only surgery or preoperative radiotherapy short term (PRT). PRT negatively impacted sexual function in both sexes. Daily activities were also statistically reduced in the PRT group. Defecation problems persisted in the PRT group. Both APR and LAR patients had similar results in the PRT group. Post APR patients scored better on their physical and psychological parameters. Worse urologic function however was seen in APR patients than those undergoing LAR.

In the Dutch Colorectal Group[67], late side effects from PRT were also analysed. There was a higher incidence of bowel dysfunction which persisted long term. Interestingly, neither stoma function nor urologic function or hospital treatment rates differ between the two groups. Patients in the radiotherapy arm also reported a higher rate of anal bleeding, mucous discharge and fecal incontinence.

THE NEED FOR A DIVERTING STOMA

The complication of anastomtotic leak can be prevented by use of a diverting stoma. In which patients, a diverting stoma becomes applicable is less clear. Obese individuals, anastomoses which are low, that is less than 6 cm from the anal verge, those under tension, male gender, donuts which are not complete, and advanced age have been cited as possible predictors of leaks. Koperna[74] made a review of 70 patients undergoing LAR and performed a cost-effectiveness analysis with a defunctioning stoma ($n = 19$) and without ($n = 51$) a defunctioning stoma. Significantly lower costs with avoidance of a stoma were seen when comparison was made with those with stoma. For LAR, 16.5% would have to be the leak rate of the anastomoses to balance the extra cost of a stoma. To limit the cost associated with a stoma, a goal of limiting the stoma rate to less than 10% of Low Anterior Resections was suggested.

Dehni[75] perfomed a study comparing leak rates in two sets of patients, those undergoing LCRA - low colorectal and those undergoing anal-pouch anastomoses. 258 consecutive patients in whom TME was performed were included in the study. A defunctioning stoma was placed in 30 of the 136 Low Colorectal Anastomoses patients and in all 122 pouch patients. Clinically detected and radiologically detected leak rates

were tabulated. In Low Colorectal Anastomoses patients with a stoma, the leak was in only two patients of 30 patients, while in patients without a stoma, the clinical leak rate was 17%. However, the leak rate was only 4.9 in patients with a pouch, which was not significantly different than the leak rate seen in those with a diversion in LCRA patients. Further advantages were seen in use of a stoma. It also decreased the clinical severity of leaks and the necessity for unscheduled surgeries to manage the leak.

The Disability Adjusted Life Years were investigated in 24 patients by O'Leary et al[76] who underwent loop ileostomy and LAR for rectal malignancy and compared with 23 patients who underwent only Low Anterior Resection. Duration of stay in hospital, time to resume normal diet, and duration of time resume work was equivalent in both groups. However, physical conditioning scores showing a reduction at 12 weeks was seen in the group with a stoma. This deficiency improved shortly after closure of the stoma. Time away from resuming work and length of stay in hospital were taken into consideration for ileostomy closure when compared with the non-diversion group. To limit some of these issues, appropriate but earlier closure of the stoma is advised.

In summary, routine use of a stoma is unnecessary as the leak rates of experienced surgeons is less, and balancing the cost–benefit ratio

would make that uneconomical. If a stoma is required, additional costs can be limited by performing the closure at the earliest. It also helps return the patient to daily work. If within 6 cm of the anal verge lies the anastomosis, a loop ileostomy is preferable. It is also advisable in those patients in whom pre-operative chemo-radiotherapy has been used. Some centres suggest closure after a leak has been excluded with a water-soluble contrast study. The loop ileostomy is typically closed at 3 months.

SUMMARY

TME has now become the standard in surgical care to proctectomy for rectal malignancy. The local control of rectal cancer has been improved with TME by utilizing a meticulous and sharp dissection that removes all the lymphatic tissue and by staying within the natural fascial containment of the rectal tumor. As the experience of the surgeon increases, blood loss, anastomotic leaks and other complications are limited. Complimentary in minimizing local and distant recurrence is use of neo-adjuvant therapy.

MATERIALS AND METHODS

Data on 50 patients with mid and low rectal malignancy planned for resectional surgery in the departments of General Surgery and Surgical Gastro-enterology from May 2011 to October 2013 were entered onto a database.

The Patient related factors such as age of the patient , the sex of the patient, Body mass index of the patient, the Disease related factors such as the distance of the tumor in cm from the anal verge as measured by colonoscopy, pT category determined after pathological examination and finally Surgery related factors such as duration of the surgery in mins, the use of neo-adjuvant therapy in the form of chemo-radiotherapy , surgical approach – laparoscopic/ open method, use of mono-polar diathermy or blunt dissection or other methods of dissection such as bipolar coagulation, harmonic device, ultrasonic dissector and presence of intra-operative complications such as pelvic haemorrhage or perforation were analysed as clinically affecting variables .

Pathology reports of those patients who underwent total mesorectal excision were examined and the TME scores added to the database. Continuous variables were analysed using ANOVA, Categorical variables were analysed using the χ^2 test. $P < 0.05$ was taken

as statistically significant. Calculations were done using SPSS 2.0 software.

TME quality data was assessed by the operating surgeon and the pathologist and recorded into a two tier grading system: complete TME was classified as ‘optimal’, while nearly complete and incomplete TME were classified as ‘sub-optimal’.

INCLUSION CRITERIA

All patients with Rectal Adenocarcinoma of the middle and lower thirds who underwent Low Anterior resection or Abdomino-perineal resection with the following criteria were included in the study:

-Histology proven by pre-operative colonoscopy

-Staging workup including CT abdomen and chest which revealed no distant metastases

-Diagnostic Laparoscopy which showed no peritoneal seeding or ascitis or unresectable disease.

EXCLUSION CRITERIA

Exclusion criteria were patients who had

- Procto-colectomy or

-Hartmann’s Procedure or,

-Local Tumor Excision

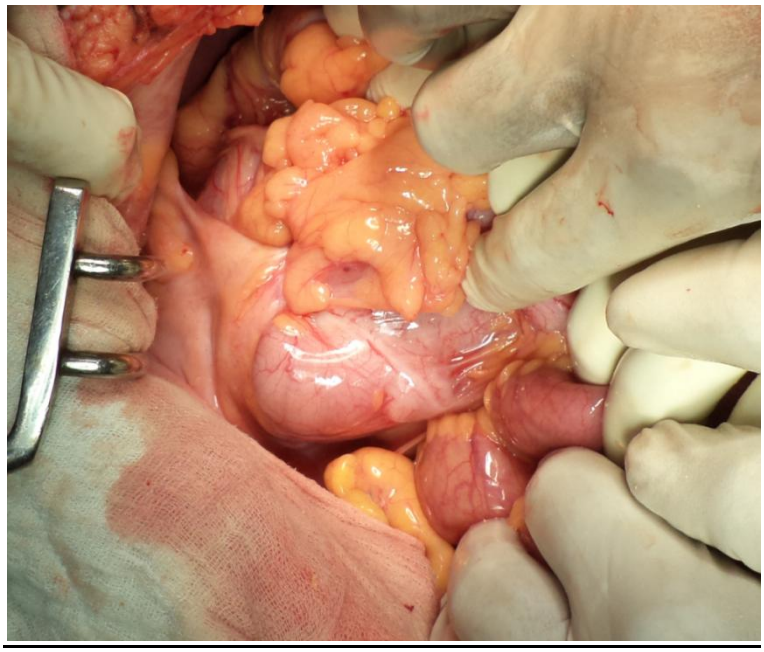


Figure 1: anterior dissection between rectum and bladder by incising rectovesical fascia

Figure 2: posterior dissection between rectum and presacral fascia preserving autonomic nerves and presacral vessels

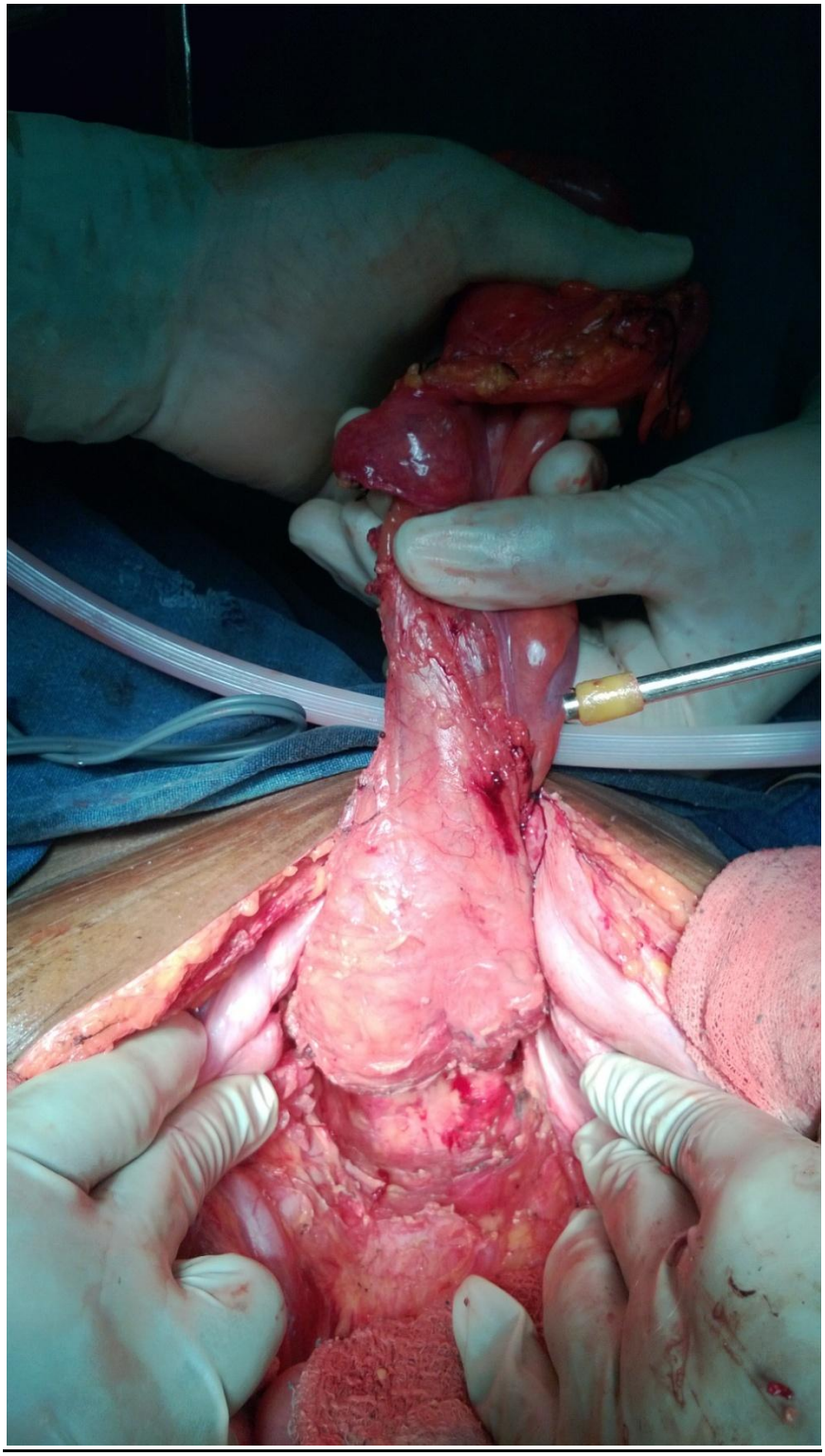


Figure 3: Posterior surface smooth, no defects in mesorectal fascia, no incisions or tearing, baby bottom appearance

Figure 4: Perineal phase of surgery after inserting purse-string suture

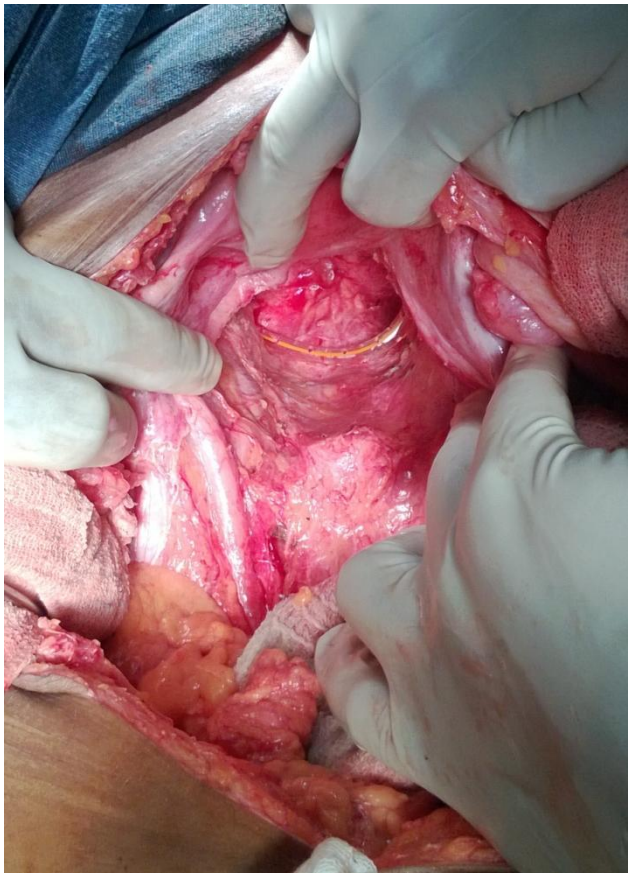


Figure 5: Abdominal phase completed with bipolar sharp dissection - no residual mesorectal tissue, secured hemostasis. Peritoneum closed.

Figure 6:'Complete TME' : Mesorectum intact and smooth, defects not deeper than 5 mm , no coning, CRM is smooth and regular

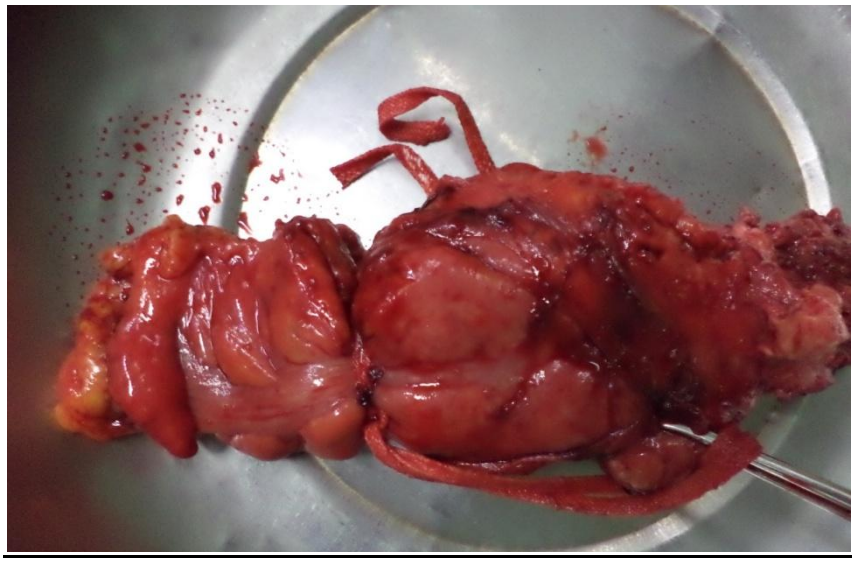
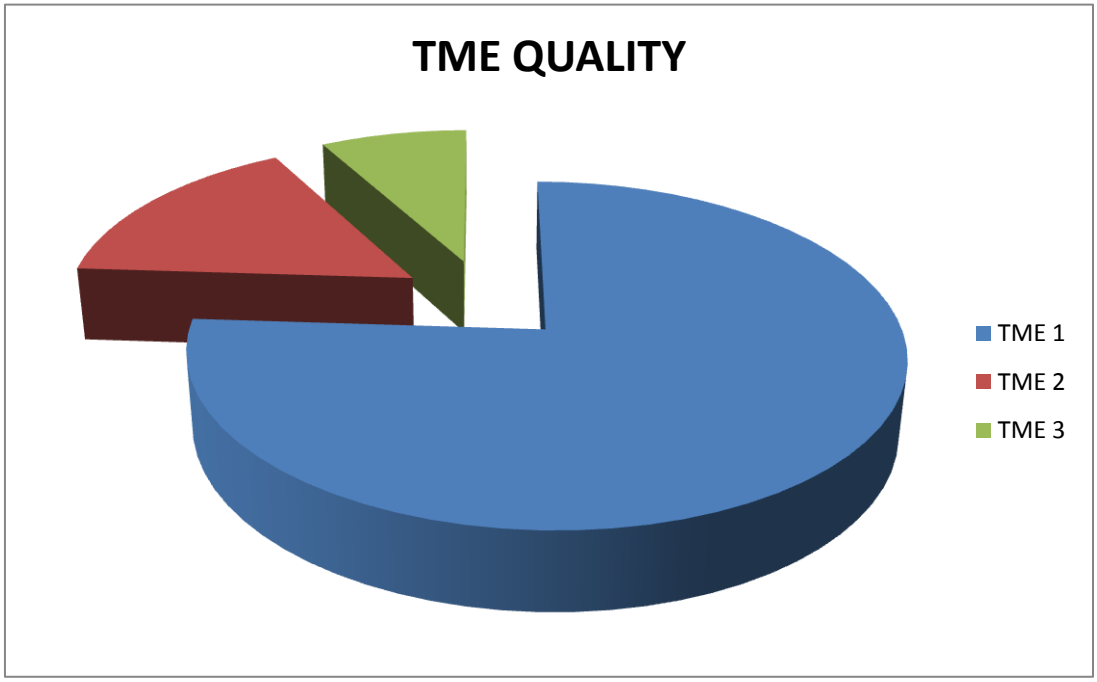


Figure 7: 'Incomplete TME' - mesorectum shows little bulk, defects beyond muscularis propria, marked coning and CRM irregularity

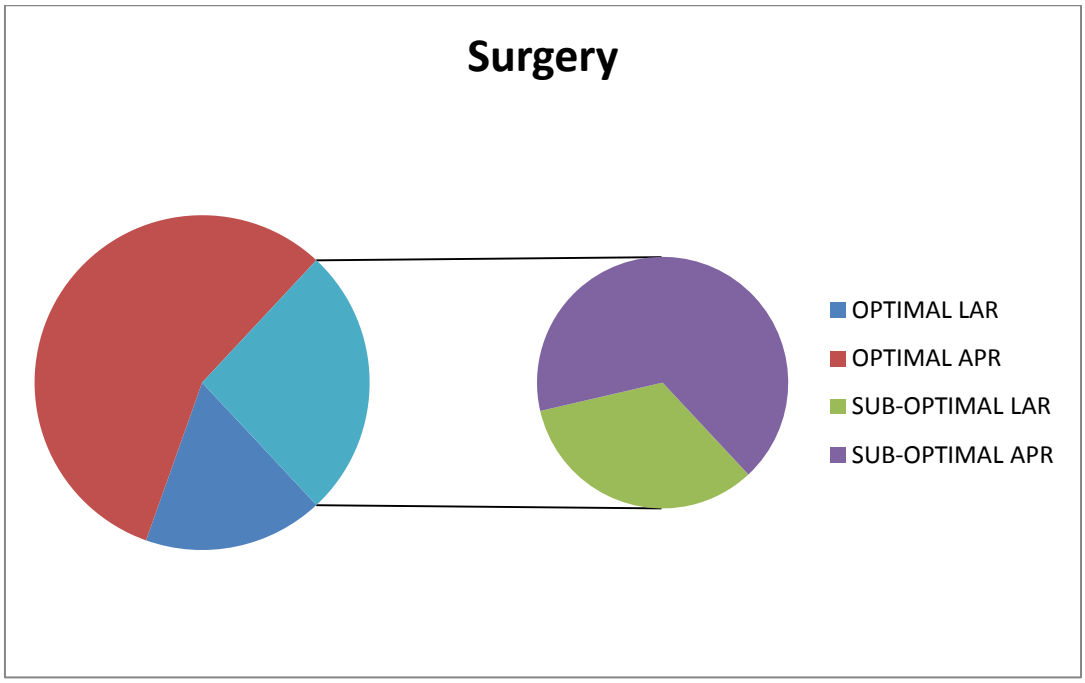
OBSERVATIONS AND RESULTS

Between May 2011 and October 2013, 50 patients who had a total mesorectal excision for adenocarcinoma of mid or lower third of the rectum were enrolled in the study. All resected specimens were scored as per specimen grading criteria as followed in PROCARE study.

TME scores were TME1 *n* = 38, TME2 *n* = 8, TME3 *n* =4.



16 patients underwent anterior resection and 34 underwent abdomino-perineal resection. Of the patients who underwent LAR, 4 patients had sub-optimal TME(25%)

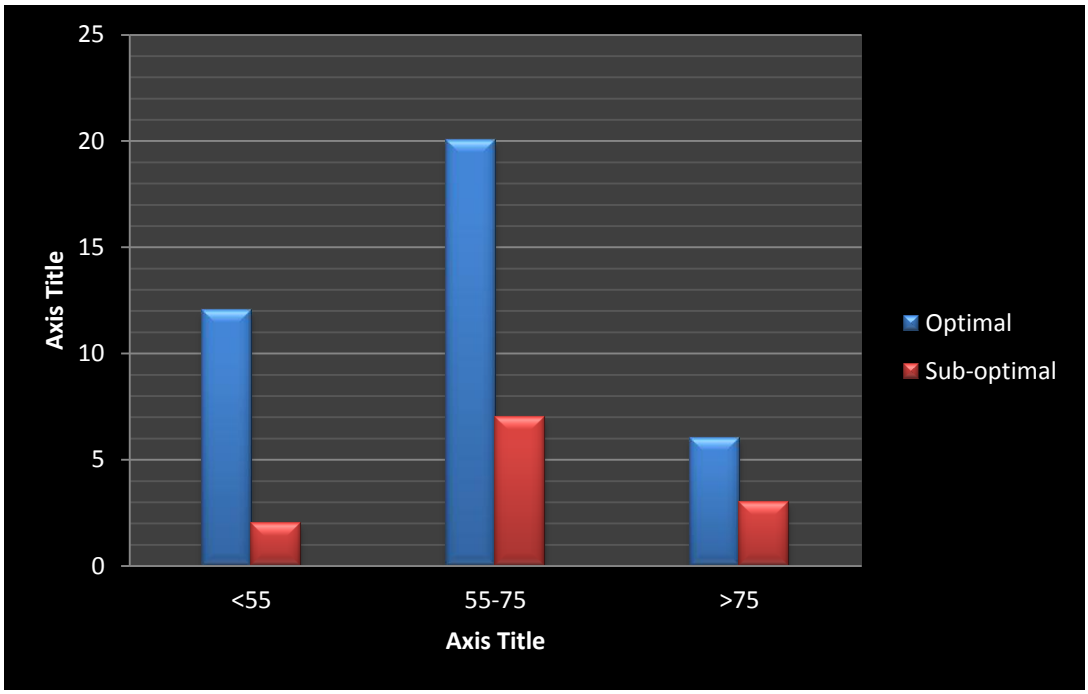


,

while of the patients who underwent APR, 8 patients(23.5%) had sub-optimal TME.

Relation of Age with TME status:

The median age of the patients was 60 years (range 54–70 years) with 14 patients less than 55 yrs and 2 patients(14.3%) with sub-optimal TME, 27 patients between 55 and 75 years and 7 patients(25.9%)

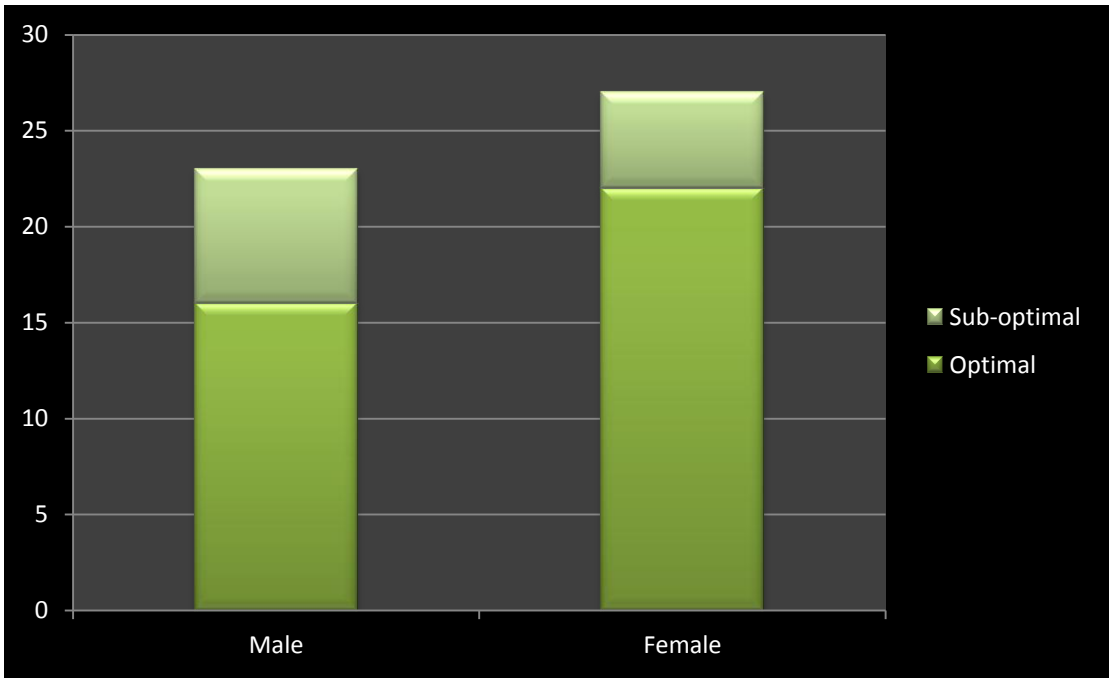


AGE	Optimal	Sub-optimal	Total
<55	12	2	14
55-75	20	7	27
>75	6	3	9

with sub-optimal TME and 9 patients over 75 years with 3 patients (33.3%) with sub-optimal TME .

Relation of Sex with TME Status:

Twenty three patients were male with 7 patients (30.5%) having sub - optimal TME, while 27 patients were

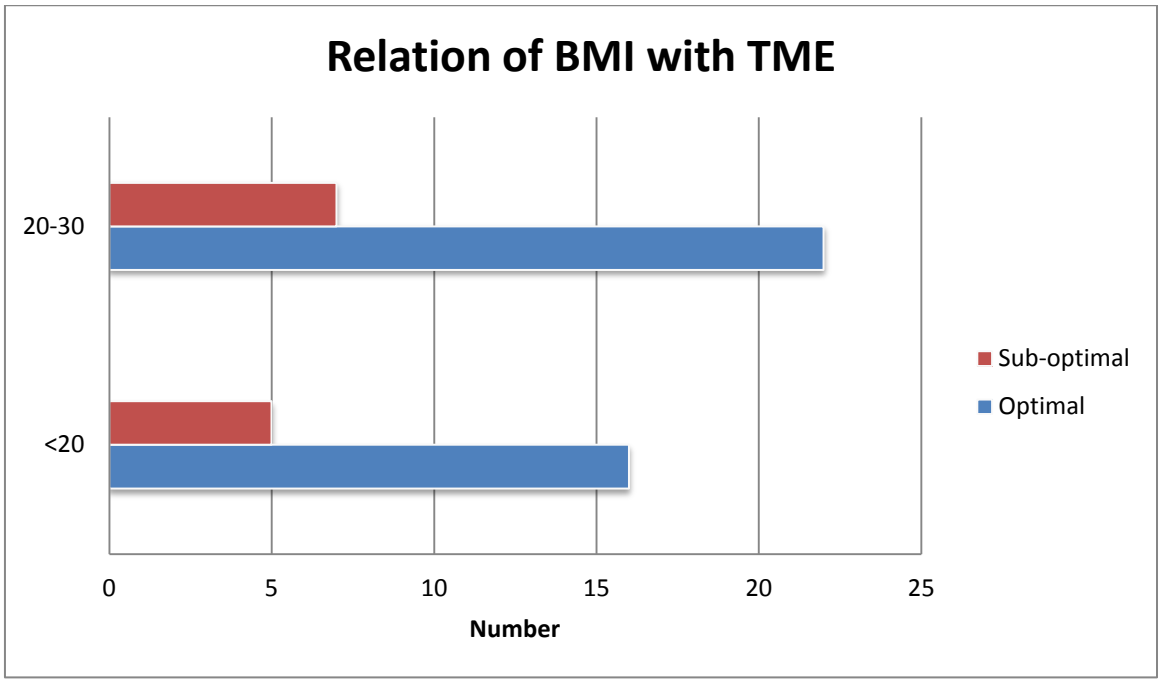


female with 5 patients (18.5%) having sub-optimal TME

Sex	Optimal	Sub-optimal	Total
Male	16	7	23
Female	22	5	27

The mean BMI was 20.46 kg/m2 with a range of 7 (17-24 kg/m2).

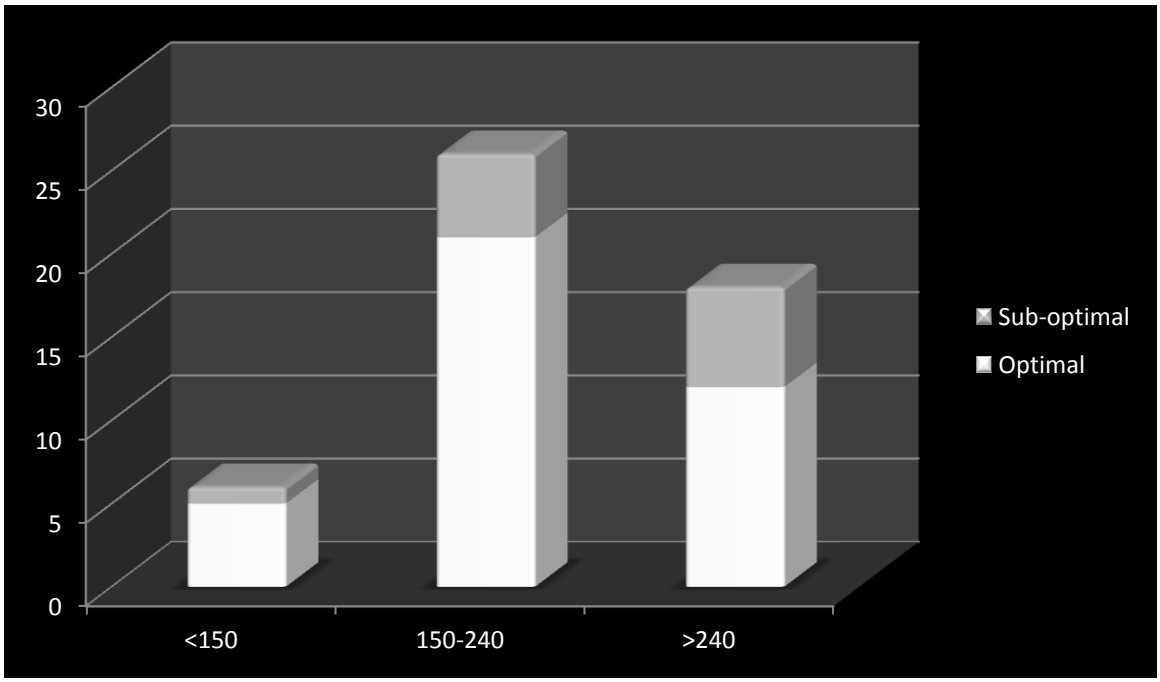
Twenty-one patients had a BMI less than 20 kg/m2 with 5 patients (23.8%) having sub-optimal TME, while 9 patients had a BMI between 20 to 25 kg/m2 with 7 patients (24.1%) having sub-optimal TME.



BMI	Optimal	Sub-optimal	Total
<20	16	5	21
20-30	22	7	29

Relation of duration of Surgery with TME status:

The mean duration of surgery was 200.3 mins with 6 patients having duration less than 150 mins and 1 patient (16.7%) with sub-optimal TME, 26 patients with duration between 150 to 240 mins with sub - optimal TME in 5 patients (19.2%),

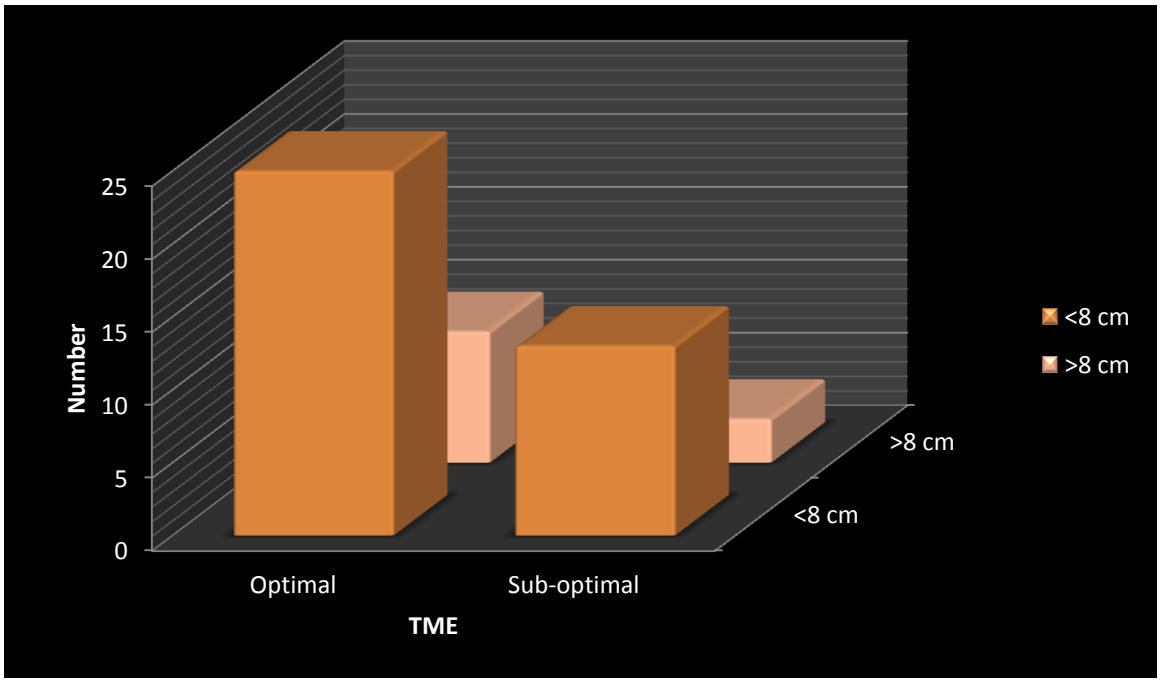


and 18 patients with surgery lasting more than 240 mins with sub-optimal TME in 6 patients (33.3%).

Duration of Surgery	Optimal	Sub-optimal	Total
<150	5	1	6
150-240	21	5	26
>240	12	6	18

Relation of distance from anal verge with TME :

Thirty-four patients were found to have tumour within 8 cm of the anal verge, with sub-optimal TME in 9 patients(26.4%),

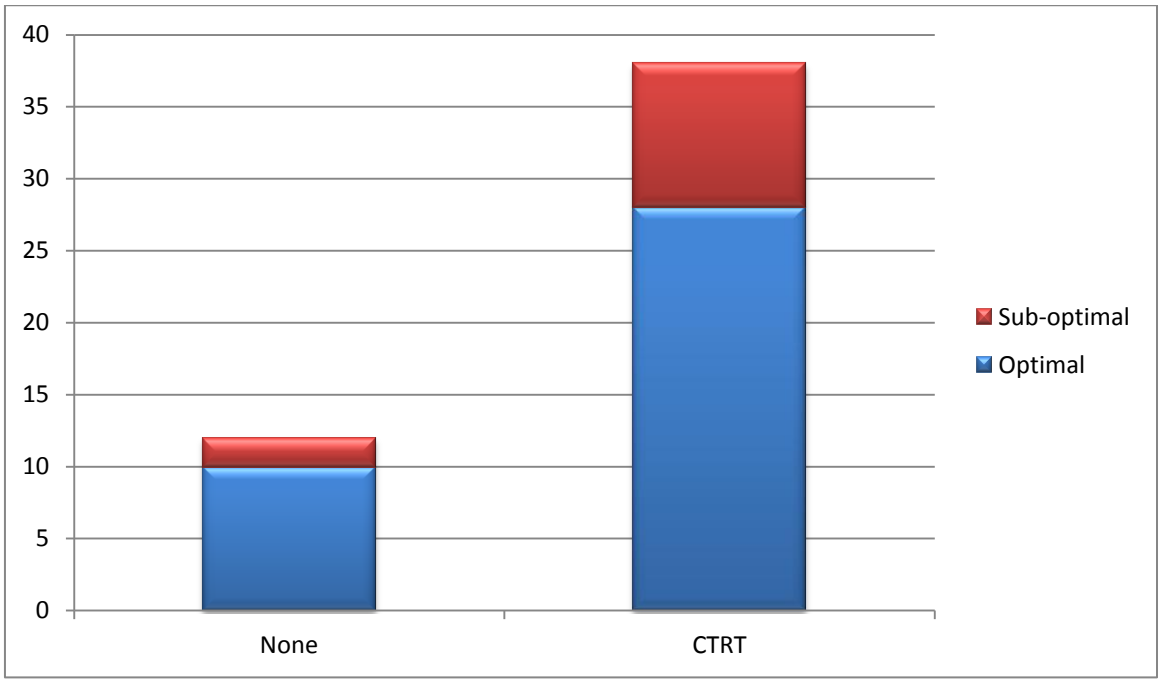


and 16 patients had tumour more than 8 cm from the anal verge with 3 patients (18.7%)having sub-optimal TME.

Distance from anal verge	Optimal	Sub-optimal	Total
<8cm	25	13	38
>8cm	9	3	12

Relation of Neo-adjuvant therapy with TME :

Thirty-eight patients were treated with preoperative chemo-radiotherapy of which 10 patients (26.3%) had sub-optimal TME, while

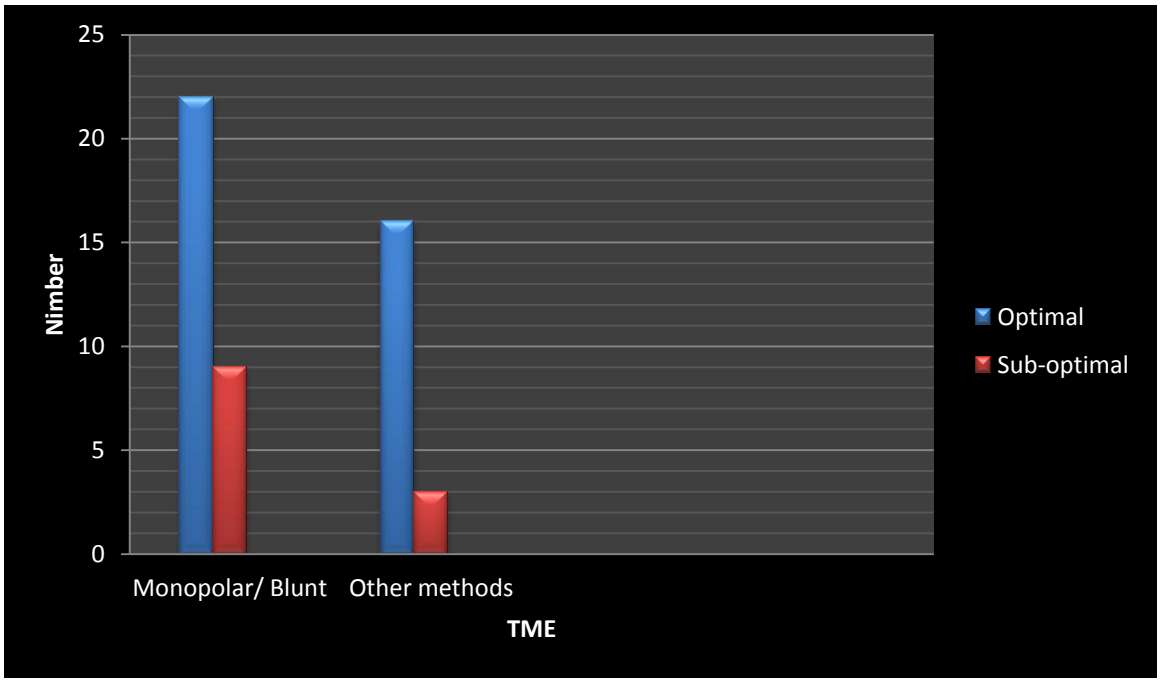


Neo-adjuvant therapy	Optimal	Sub-optimal	Total
None	10	2	12
CTRT	28	10	38

12 patients did not require neo-adjuvant therapy, in which 2 patients (22.2%) had sub-optimal TME.

Relation of dissection method with TME:

Monopolar diathermy was used as the primary dissecting modality in 31 patients with 9 patients (26.3%) showing sub-optimal TME, while

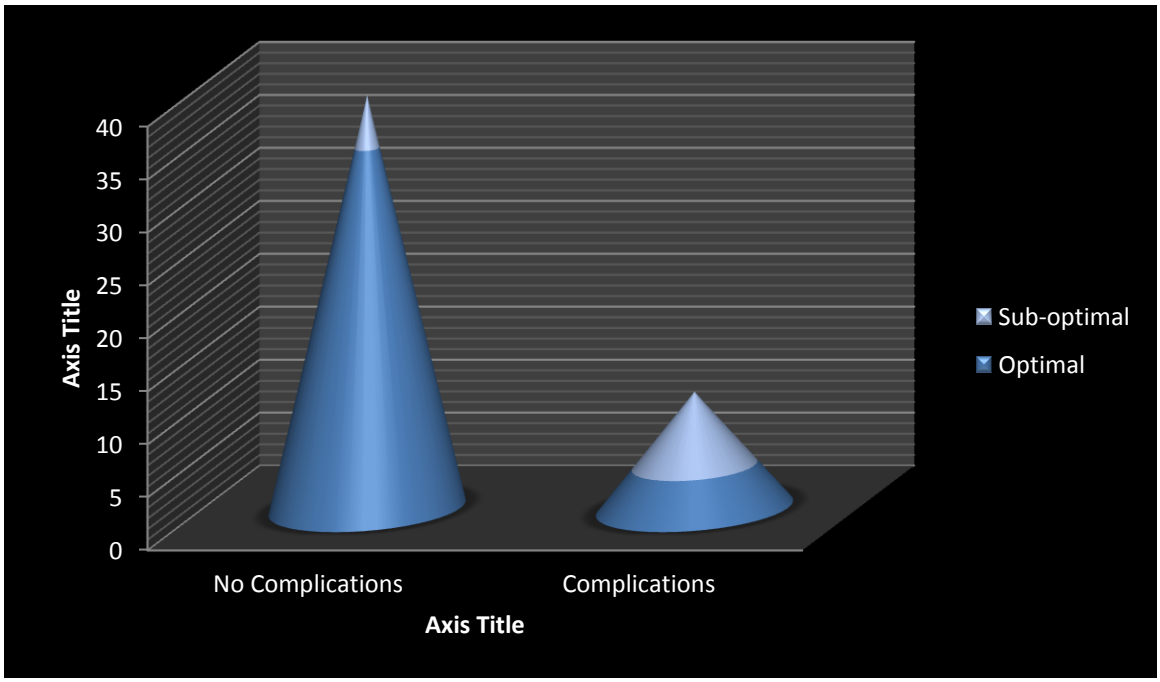


19 patients had other forms of dissection (bipolar diathermy, harmonic scalpel) with 3 patients (15.8%) having sub-optimal TME .

Method of dissection	Optimal	Sub-optimal	Total
Monopolar/ Blunt	22	9	31
Other methods	16	3	19

Relation of Intra-op complications with TME:

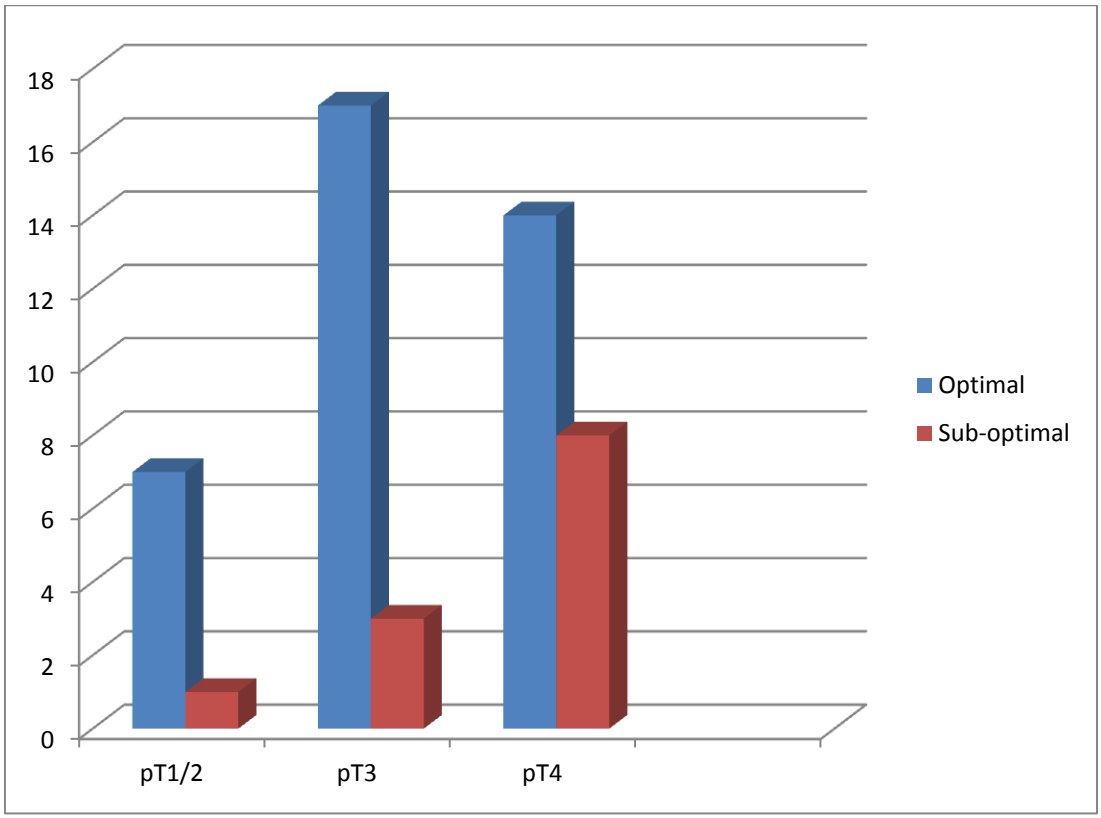
Intra-operative complications were seen in 11 patients with 7 patients (63.7%) having sub-optimal TME, While no complications were seen in 39 patients with sub-optimal TME in 5 of them.



Complications	Optimal	Sub-optimal	Total
No Complications	34	5	39
Complications	4	7	11

Relation of PT Category with TME:

Pathological examination of the specimen for pT stage showed 8 patients had a category pt1/2 with 1 patient(12.5%) having sub-optimal TME, 20 patients had a pT3 with 3 patients (15%)

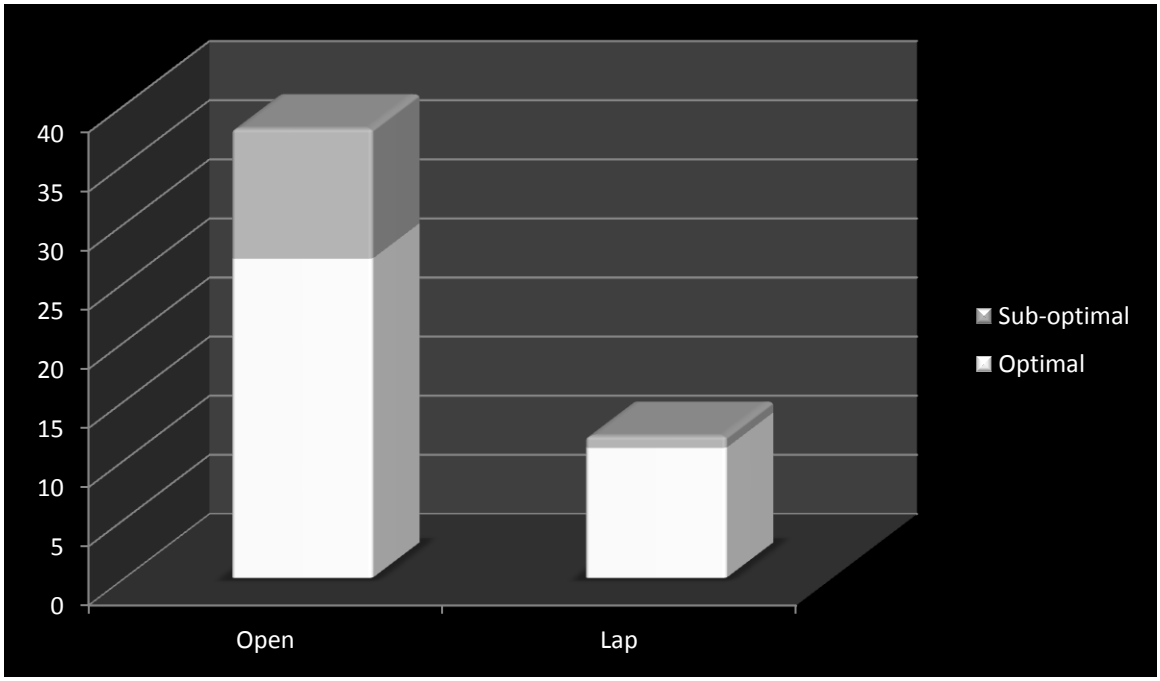


having sub-optimal TME, and 22 patients fell into pT4 with 8 patients(36.3%) having sub-optimal TME.

pT Stage	Optimal	Sub-optimal	Total
pT1/2	7	1	8
pT3	17	3	20
pT4	14	8	22

Relation of surgical approach with TME:

. Laparoscopic approach was used in 12 patients with 1 patient (8.3%) having sub-optimal TME, while Open approach was followed in 38 patients with 11 patients (28.9%) having sub-optimal TME.



Surgical method	Optimal	Sub-optimal	Total
Open	27	11	38
Lap	11	1	12

CONCLUSION AND RECOMMENDATIONS

Pathological tumour category T4 was more significantly associated ($p<0.05$) with sub-optimal TME than T3 or T1/2 tumours which was due to proximity of CRM to the tumor. Also significant ($p<0.05$) were presence of intra-operative complications and surgery lasting longer than 240 mins. Use of monopolar or blunt dissection was also independently associated with moderate or poor TME quality ($p<0.05$).

Total mesorectal excision scores were not statistically influenced by gender of patients ($p=0.213$), both male and female patients producing comparable TME. Though male pelvis being narrower was suggested in previous studies to result in a poorer TME, no difference was seen in this study.

Age of the patients ($p=0.288$) also did not affect TME with patients across all age groups producing no difference statistically. TME also did not vary with BMI ($p=0.973$) but this was not significant as all patients fell within a narrow BMI range in this study.

The distance of tumour from anal verge ($p=0.578$) did not affect TME, be it mid or a low rectal tumour, although previous studies

demonstrated a poorer TME with low rectal tumours due to coning, but this was not seen in our study.

The type of surgical approach (p=0.72) or preoperative chemo-radiotherapy (p=0.376) also did not affect TME with equivalent results in both groups. This can be explained due to decrease in size of the tumor with neoadjuvant chemoradiotherapy which provided an adequate CRM.

Hence, more care and meticulous dissection is advisable in locally advanced T4 lesions to ensure adequate CRM. Also, an inadequate TME can be anticipated in those surgeries where complications are encountered as a result of which duration progresses beyond 4 hours. Since these variables are more difficult to control, the variable which can be controlled is alteration of dissection from monopolar or blunt dissection to bipolar or harmonic dissection.

Overall, though many variables are found to influence TME in resected specimens, the expertise of the surgeon is also a factor. Control of all these factors helps in providing optimal TME, which promises the lowest local and distant recurrence in surgery for rectal cancer at this time.

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ANNEXURES

AJCC TNM Staging System for Colorectal Cancer

Primary Tumor (T)	
TX	Primary tumor cannot be assessed
T0	No evidence of primary tumor
Tis	Carcinoma in situ: intraepithelial
T1	Tumor invades submucosa
T2	Tumor invades muscularis propria
T3	Tumor invades through the muscularis propria into the subserosa, or into nonperitonealized pericolic or perirectal tissues
T4	Tumor directly invades other organs or structures and/or perforates visceral peritoneum
Regional Lymph Nodes (N)	
NX	Regional lymph nodes cannot be assessed
N0	No regional lymph node metastasis
N1	Metastasis in 1 to 3 regional lymph nodes
N2	Metastasis in 4 or more regional lymph nodes

Distant Metastasis (M)	
MX	Distant metastasis cannot be assessed
M0	No distant metastasis
M1	Distant metastasis

Stage Grouping

STAGE	T	N	M	DUKES	MAC
0	Tis	N0	M0		
I	T1	N0	M0	A	A
	T2	N0	M0	A	B1
IIA	T3	N0	M0	B	B2
IIB	T4	N0	M0	B	B3
IIIA	T1-T2	N1	M0	C	C1
IIIB	T3-T4	N1	M0	C	C2/C3
IIIC	Any T	N2	M0	C	C1/C2/C3
IV	Any T	Any N	M1		D

PATHOLOGICAL GRADING OF TME

Table 1. Grading of the quality of mesorectal excision in TME specimens as proposed in the PROCARE guidelines. Both the specimen as a whole (fresh) and transverse slices (after fixation) should be examined in order to allow adequate evaluation of the mesorectal excision.	
Smooth, regular	- intact mesorectum with only minor irregularities of a smooth mesorectal surface - no defect deeper than 5 mm - no coning toward the distal margin of the specimen* - a smooth circumferential resection margin on slicing
Mildly irregular	- moderate bulk to the mesorectum, but irregularity of the mesorectal surface - moderate coning of the specimen allowed* - the muscularis propria invisible at every site, with the exception of the insertion of the levator muscles
Severely irregular	- little bulk to the mesorectum with defects down onto the muscularis propria and/or very irregular circumferential resection margin on slicing

PROFORMA

- NAME : SL. NO:
- AGE /SEX:
- ADDRESS WITH CONTACT NUMBER:
- IP NO:
- DATE OF ADMISSION:
- DATE OF SURGERY:
- DATE OF DISCHARGE:

HISTORY OF PRESENTING ILLNESS:

- MASS PER RECTUM:
    - Onset-
    - Duration-
    - Progress-
    - Persistent or intermittent-

- PAIN:
    - Site-
    - Duration-
    - Nature-
    - Aggravating/relieving factors-

- DISCHARGE FROM THE ANUS, IF ANY:
- BLEEDING PER RECTUM, IF ANY:
- PAIN ABDOMEN
- CONSTIPATION/ DIARRHOEA

PAST HISTORY:

WHETHER A KNOWN CASE OF DM/HYPERTENSION/ASTHMA/TB/EPILEPSY/CARDIAC ILLNESS

H/O SIMILAR EPISODES IN THE PAST, IF ANY:

H/O ANAL/RECTAL SURGERIES IN THE PAST, IF ANY:

H/O TRAUMA TO PERINEAL REGION IN THE PAST, IF ANY

H/O MAJOR ILLNESS/ HOSPITAL ADMISSIONS, IF ANY

PERSONAL HISTORY:

WHETHER HE WAS A SMOKER OR AN ALCOHOLIC

FAMILY HISTORY:

DIETARY HISTORY:

TREATMENT HISTORY:

USE OF NEO-ADJUVANT CHEMOTHERAPY

CLINICAL EXAMINATION:

GENERAL EXAMINATION:

VITALS:

BMI:

SYSTEMIC EXAMINATION:

CVS

RS

PER ABDOMEN

CNS

LOCAL EXAMINATION:

- PR:
- PROCTOSCOPY:

CLINICAL DIAGNOSIS:

INVESTIGATIONS:

- SIGMOIDOSCOPY:
- COLONOSCOPY
- CECT ABDOMEN & PELVIS:
- ROUTINE INVESTIGATIONS(CBC,RFT,CXR,ECG)
- OTHER INVESTIGATIONS(IF ANY):

FINAL DIAGNOSIS:

SURGERY DONE:

TYPE OF SURGERY:

SURGICAL APPROACH:

DURATION OF SURGERY:

TUMOUR DISTANCE FROM ANAL VERGE:

TECHNIQUES OF PELVIC DISSECTION:

(BLUNT DISSECTION/ MONOPOLAR COAGULATION VS OTHER TECHNIQUES – BIPOLAR COAGULATION, HARMONIC DEVICE, WATERJET DISSECTION DEVICE, ULTRASOUND DISSECTOR, BIPOLAR VESSEL SEALER DEVICE)

PRESENCE OF INTRA-OPERATIVE COMPLICATIONS:

POST OPERATIVE COMPLICATIONS, IF ANY:

HPE:

PT- PATHOLOGICAL TUMOUR STAGING (pT1/T2, pT3, pT4)

TME OPTIMAL vs TME SUBOPTIMAL

FOLLOW UP:

மலக்குடல் புற்றுநோய் அறுவை சிகிச்சையில் மலக்குடலையும் அதனை ஒட்டியுள்ள பகுதி (மீசோ ரெக்டம்) மற்றும் நிணநீர் முடிச்சுக்களையும் முழுமையாக அகற்றுவதில் தரத்தை உயர்த்தும் காரணங்களை கண்டரியும் ஆய்வு

ஆய்வாளர்: டாக்டர். ராபின் பிரபு
முதுநிலை பட்டமேற்படிப்பு மாணவர்.
அறுவை சிகிச்சை பட்டப்படிப்பு.

வழிகாட்டிபேராசிரியரி. டாக்டர். விஸ்வனாதன்
அறுவை சிகிச்சை பேராசிரியர்.
அரசு ஸ்டான்லி மருத்துவமனை.

சுய ஒப்புதல் படிவம்

பெயர்: வயது: உள்ளிருப்பு எண்:

இந்த மருத்துவ ஆய்வின் விவரங்கள் எனக்கு விளக்கப்பட்டது என்னுடைய சந்தேகங்களைக் கேட்கவும், அதற்கான தகுந்த விளக்கங்களைப் பெறவும் வாய்ப்பளிக்கப்பட்டது

நான் இவ்வாய்வில் தன்னிச்சையாகத் தான் பங்கேற்கிறேன் எந்த காரணத்தினாலும், எந்த கட்டத்திலும், எந்த சட்டசிக்கலுக்கும் உட்படாமல் இந்த ஆய்விலிருந்து விலகிக்கொள்ளலாம் என்றும் அறிந்துக் கொண்டேன்.

நான் ஆய்விலிருந்து விலகிக்கொண்டாலும் ஆய்வாளர் என்னுடைய மருத்துவ அறிக்கைகளைப் பார்ப்பதற்கோ அல்லது உபயோகிக்கவோ என் அனுமதி தேவையில்லை என அறிந்து கொள்கிறேன் என்னைப் பற்றிய தகவல்கள் ரகசியமாகப் பாதுகாக்கப்படும் என்பதை அறிவேன்.

இந்த ஆய்வின் மூலம் கிடைக்கும் தகவல்களையும் பரிசோதனை முடிவுகளையும், ஆய்வாளர் அவர் விருப்பத்திற்கேற்ப எவ்விதமாகப் பயன்படுத்திக் கொள்ளவும் அதை பிரசுரிக்கவும் என் முழுமனதுடன் சம்மதிக்கிறேன்.

இந்த ஆய்வின் பங்குக்கொள்ள ஒப்புக்கொள்கிறேன். எனக்குக் கொடுக்கப்பட்ட அறிவுரைகளின்படி நடந்துக் கொள்வதுடன் ஆய்வாளருக்கு உண்மையுடன் இருப்பேன் என்றும் உறுதியளிக்கிறேன். என் உடல் நலம் பாதிக்கப்பட்டாலோ அல்லது எதிர்பாராத வழக்கத்திற்கு மாறான நோய்க்குறி தென்பட்டாலோ உடனே அதை தெரிவிப்பேன் என் உறுதி கூறுகிறேன்.

இந்த ஆய்வில் எனக்கு எவ்வித மற்றும் அனைத்துப் பரிசோதனைகளையும் சிகிச்சைகளையும் மேற்கொள்ள நான் முழுமனதுடன் சம்மதிக்கிறேன்.

இப்படிக்கு.

நோயாளியின் கையொப்பம்
(பெயர்)

ஆய்வாளர் கையொப்பம்
(டாக்டர்.ராபின் பிரபு)

மலக்குடல் புற்றுநோய் அறுவை சிகிச்சையில் மலக்குடலையும் அதனை ஒட்டியுள்ள பகுதி (மீசோ ரெக்டம்) மற்றும் நிணநீர் முடிச்சுக்களையும் முழுமையாக அகற்றுவதில் தரத்தை உயர்த்தும் காரணங்களை கண்டரியும் ஆய்வு

ஆய்வாளர் : டாக்டர். ராபின் பிரபு
முதுநிலை பட்டமேற்படிப்பு மாணவர்.
அறுவை சிகிச்சை பட்டபடிப்பு.

வழிகாட்டிபேராசிரியரி. டாக்டர். விஸ்வனாதன்
அறுவை சிகிச்சை பேராசிரியர்.
அரசு ஸ்டான்லி மருத்துவமனை.

பங்கேற்பாளரின் தகவல் படிவம்

நீங்கள் இந்த ஆய்வில் பங்கேற்க அழைக்கப்படுகிறீர்கள்.

இந்த ஆய்வில் பங்கேற்கும் முன்னர். இதன் நோக்கத்தையும் முறைகளையும் இதனால் ஏற்படக்கூடிய பின்விளைவுகள் ஏதேனையும் நீங்கள் அறிந்துக் கொள்ள ஆய்வாளர் அளிக்கும் ததகவல் பின்வருமாறு

வயிறு மற்றும் குடல் அறுவை சிகிச்சைக்கு உட்படுத்தப்பட இருக்கும் நோயாளிகள் மட்டுமே இந்த ஆய்வில் எடுத்துக் கொள்ளப்படுவீர்கள். உங்கள் நோயின் முழு வரலாறும். உங்களின் முழு உடல் பரிசோதனையும் தெளிவாகவும் விரிவாகவும் பதிவு செய்யப்படும் அடிப்படை இரத்த பரிசோதனை மற்றும் நுண்கதிரியல் பரிசோதனைகளின் முடிவுகள் ஏற்றவாறுபதியப்படும். அறுவை சிகிச்சைக்கு முன்னும். பின்னும் மற்றும் அறுவை சிகிச்சையின் பொழுதும் உங்களிடம் ஏற்படும் உடல் நிலை மாற்றாங்கள் பதிவு செய்யப்படும்.

இந்த ஆய்வின் முடிவுகள் மருத்துவ காரணங்களுக்காகவும் மருத்துவக கல்விக்காகவும் பயன்படுத்தப்படும். இந்த ஆய்வு பற்றிய சந்தேகங்களுக்கு உரிய முறையில் விளக்கமளிக்கப்படும். தங்களைப் பற்றிய தகவல்கள் ரகசியமாகப் பாதுகாக்கப்படும்.

இந்த ஆய்விலிருந்து எப்போழுது வேண்டுமானாலும் தாங்கள். எவ்வித முன்னறிவிப்பின்றியும். எவ்வித சட்டச் சிக்கலும் இன்றியும் விலகிக்கொள்ளலாம். இந்த ஆய்வில் பங்கேற்கமாறு கேட்டுக் கொள்கிறேன்.

நன்றி.

ஆய்வாளர் கையொப்பம்
(டாக்டர்.ராபின் பிரபு)

நோயாளியின் கையொப்பம்
(பெயர்)

INSTITUTIONAL ETHICAL COMMITTEE,
STANLEY MEDICAL COLLEGE, CHENNAI-1

Title of the Work : A study on factors influencing the quality of total mesorectal excision

Principal Investigator : Dr.I. Robin Prabhu

Designation : PG in M.S.(Gen.Sur)

Department : Department of General Surgery
Government Stanley Medical College,
Chennai-10

The request for an approval from the Institutional Ethical Committee (IEC) was considered on the IEC meeting held on 08.04.2013 at the Council Hall, Stanley Medical College, Chennai-1 at 2PM

The members of the Committee, the secretary and the Chairman are pleased to approve the proposed work mentioned above, submitted by the principal investigator.

The Principal investigator and their team are directed to adhere to the guidelines given below:

1. You should inform the IEC in case of changes in study procedure, site investigator investigation or guide or any other changes.
2. You should not deviate from the area of the work for which you applied for ethical clearance.
3. You should inform the IEC immediately, in case of any adverse events or serious adverse reaction.
4. You should abide to the rules and regulation of the institution(s).
5. You should complete the work within the specified period and if any extension of time is required, you should apply for permission again and do the work.
6. You should submit the summary of the work to the ethical committee on completion of the work.

18/12/13

MEMBER SECRETARY,
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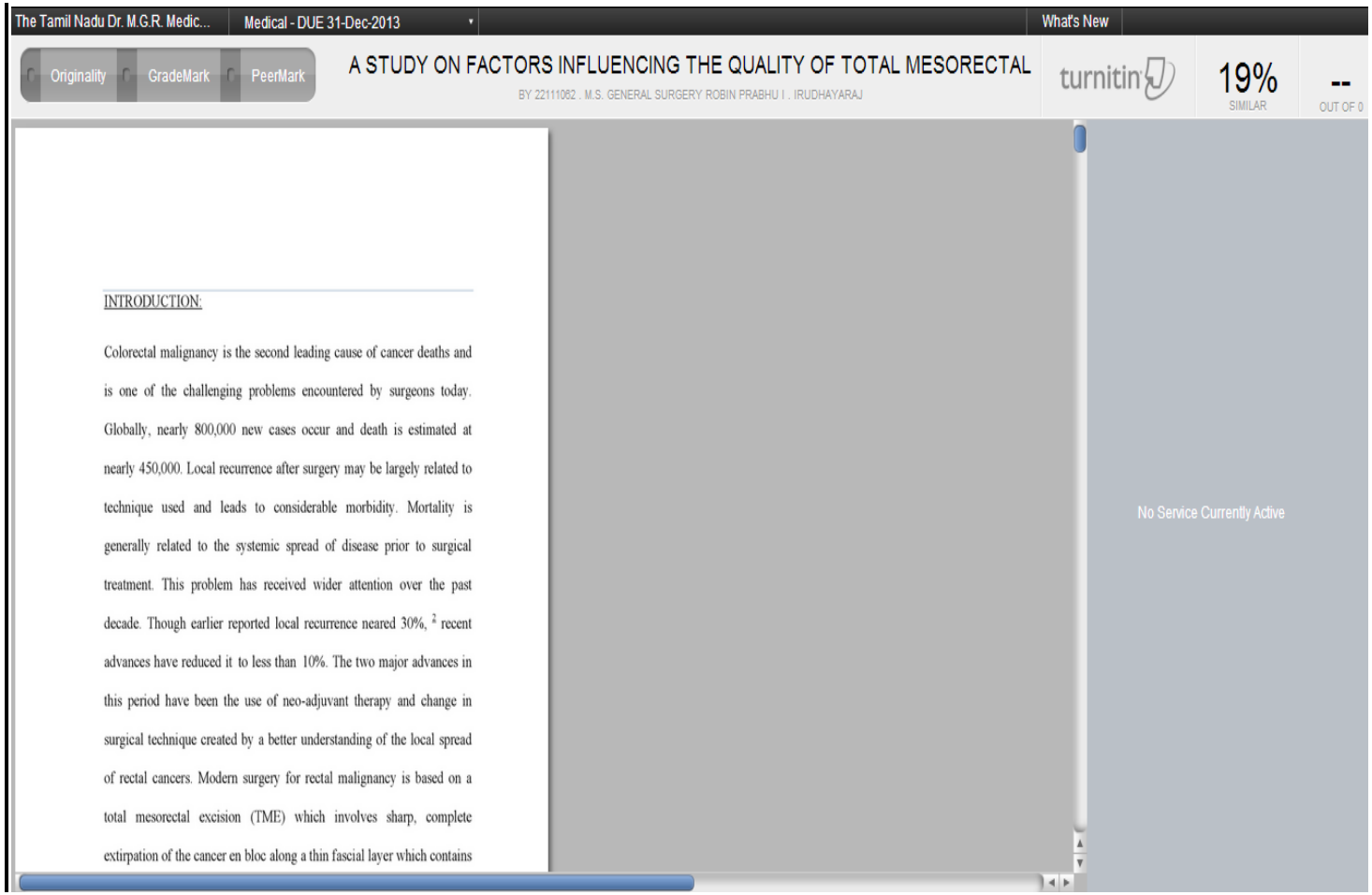
The Tamil Nadu Dr. M.G.R. Medic...
Medical - DUE 31-Dec-2013
What's New
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A STUDY ON FACTORS INFLUENCING THE QUALITY OF TOTAL MESORECTAL
BY 22111062 . M.S. GENERAL SURGERY ROBIN PRABHU I . IRUDHAYARAJ
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INTRODUCTION:
Colorectal malignancy is the second leading cause of cancer deaths and is one of the challenging problems encountered by surgeons today. Globally, nearly 800,000 new cases occur and death is estimated at nearly 450,000. Local recurrence after surgery may be largely related to technique used and leads to considerable morbidity. Mortality is generally related to the systemic spread of disease prior to surgical treatment. This problem has received wider attention over the past decade. Though earlier reported local recurrence neared 30%, [2] recent advances have reduced it to less than 10%. The two major advances in this period have been the use of neo-adjuvant therapy and change in surgical technique created by a better understanding of the local spread of rectal cancers. Modern surgery for rectal malignancy is based on a total mesorectal excision (TME) which involves sharp, complete extirpation of the cancer en bloc along a thin fascial layer which contains
No Service Currently Active

,MASTER CHART

SL. NO.	NAME	IP NO	AGE (YRS)	SEX (M/F)	BMI (KG /M2)	DISTANCE FROM ANAL VERGE (CM)	NEO-ADJUVANT THERAPY (CTRT/ NO)	MONO-POLAR USED (Y/N)	DURATION OF SURGERY (MINS)	INTRA-OP COMPLICATIONS (Y/N)	PATHOLOGICAL TUMOR STAGE (PT1/2/3/4)	METHOD OF SURGERY (LAP/ OPEN)	OPTIMAL TME (Y/N)
25	GOVINDAMMAL	36633	62	f	19	5	ctrt	y	190	n	4	open	y
26	SATYA BALU	11985	70	m	24	6	n	n	170	n	2	lap	n
27	GUNASEELAN	39051	77	m	18	3	n	n	170	n	2	lap	y
28	JAGADHA	11225	70	f	21	11	ctrt	n	240	n	3	open	y
29	JAGANATHAN	34050	71	m	21	9	n	y	250	n	3	open	n
30	GANESAN	13947	69	m	17	5	n	n	250	n	2	lap	y
31	DEVI	45240	61	f	21	10	n	n	170	n	1	lap	y
32	CHENNAIAH	19275	78	m	19	2	n	y	250	n	2	lap	y
33	MUTHURSHA	48250	74	m	19	7	ctrt	y	200	y	4	open	n
34	SAMPOORNAM	42490	73	f	22	4	n	y	140	n	2	lap	y
35	DURAI SAMY	48344	72	m	17	11	ctrt	y	190	n	3	open	y
36	JAYAMMA	33294	79	f	19	7	ctrt	n	260	n	3	open	n
37	VASANTHA	47816	55	f	21	10	ctrt	y	180	n	3	open	y
38	RUTTAMMAL	26283	68	f	23	5	ctrt	y	260	n	3	open	y
39	JAYALAKSHMI	50844	77	f	17	5	ctrt	y	210	y	4	open	n
40	ASHOK KUMAR	22839	70	m	24	8	ctrt	n	170	n	3	open	y
41	SUSILA	52129	59	f	22	6	ctrt	n	140	n	2	open	y
42	MUMTAZ	27183	67	f	24	11	ctrt	n	170	n	4	open	y
43	NAGAMMA	16114	80	f	18	6	ctrt	y	265	y	3	open	n
44	RANGASAMY	23793	69	m	22	6	ctrt	y	160	n	4	open	y
45	LOGAMBAL	11674	62	f	24	11	ctrt	n	250	y	4	open	y
46	MALLIGA	33183	69	f	19	7	ctrt	y	140	n	2	lap	y
47	IYAPILLAI	14140	67	m	23	7	ctrt	y	180	n	3	open	y
48	RAMALINGAM	48927	58	m	19	5	n	y	190	n	2	lap	y
49	THIRUPURAMMAL	14136	68	f	22	3	n	y	170	n	2	lap	y
50	NAGARATHNAM	42379	74	f	19	6	ctrt	y	250	n	3	open	y